# HIT Standards Committee
# Final Transcript
# March 27, 2012

## Presentation

**Operator**
Ms. Deering, all lines are bridged.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Good morning, everyone. This is Mary Jo Deering in the Office of the National Coordinator for Health IT. This is a meeting of the HIT Standards Committee. It is a public meeting and there will be an opportunity for public comment at the end. I would ask all members to identify themselves when they're speaking because there will be a transcript made. I'll begin by taking the roll. Jonathan Perlin?

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
Good morning.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
John Halamka?

**John Halamka – Harvard Medical School – Chief Information Officer**
Good morning.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Farzad Mostashari?

**Farzad Mostashari – Office of the National Coordinator for Health Information Technology – National Coordinator for Health Information Technology**
Right here.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Dixie Baker? Anne Castro?

**Anne Castro – Blue Cross Blue Shield South Carolina – Chief Design Architect**
Here.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Chris Chute?

**Christopher Chute – Mayo Clinic – VC Data Gov. & Health IT Standards**
Present.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Tim Cromwell? John Derr?

**John Derr – Golden Living LLC – Chief Technology Strategic Officer**

Here.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Carol Diamond?

**Rebekah Rockwood – Markle Foundation – Manager, Health**
Rebekah Rockwood for Carol.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Lorraine, I think you're on.

**Lorraine Doo – CMS – Sr. Policy Advisory Office eHealth Standards & Services**
Yes, I am.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Floyd Eisenberg?

**Floyd Eisenberg – National Quality Forum**
Present.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Jamie Ferguson?

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**
Here.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Leslie Kelly Hall?

**Leslie Kelly Hall – Healthwise**
Here.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Martin Harris?

**Martin Harris – Cleveland Clinic – Chief Information Officer**
Here.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Stan Huff? Kevin Hutchinson?

**David Kates – Prematics, Inc. – Vice President Product Management**
David Kates for Kevin Hutchinson.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Thank you. Liz Johnson?

**Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics**
Here.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Rebecca Kush?

**Rebecca Kush – CDISC – CEO & President**
Here.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Arien Malec?

**Arien Malec – RelayHealth – VP, Product Management**
I'm here.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
... . David McCallie?

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**
Here.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Nancy Orvis?

**Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief**
Present.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Marc Overhage? Wes Rishel?

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**
Here.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Chuck Romine? Cris Ross? Walter Suarez? Sharon Terry?

**Sharon Terry – Genetic Alliance – President & CEO**
Here.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Jim Walker?

**Jim Walker – Geisinger Health Systems – Chief Health Information Officer**
Here.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Okay, thank you. And back to you, Jon.

**Walter Suarez – Kaiser Permanente – Director, Health IT Strategy**
This is Walter Suarez. I'm here. Sorry, I was on mute.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Oh, good. Thank you.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
Terrific, good morning. I'm going to make some introductory comments momentarily, but I want to thank everybody for joining this morning. I appreciate everyone calling in and I appreciate your help with the phone etiquette, that being if there's noise in your background please help by muting your line and if you need to step away, please mute, not hold, or we'll hear your hold music or other information that occurs with your hold, so mute not hold. If you want to speak up, please do make yourself evident to John Halamka or myself.

This is a hugely exciting time and it feels just ripe with the energy of spring and the energy of having gone through one stage of Meaningful Use and well into the work of reviewing the NPRM for all of the aspects surrounding Stage 2 of Meaningful Use. I appreciate all of the efforts that have gone on since we last met. Let me reserve a moment for John Halamka and myself to make some comments, but first turn immediately over to Dr. Farzad Mostashari, with great thanks for his being here and his terrific energy and leadership. Good morning, Farzad.

**Farzad Mostashari – Office of the National Coordinator for Health Information Technology**
Thank you so much. Thank you. I wanted to actually make an announcement first about our new Judy Sparrow; MacKenzie Robertson is going to be transitioning into the role of our Federal Advisory Committee Coordinator, and with great, great, great, great, great thanks to Mary Jo Deering, who has stepped into the breach with Judy Sparrow's departure, and we really did not miss a beat during this incredibly busy and consequential period. So Mary Jo, our thanks to you and our welcome to MacKenzie, who you will help transition into this role over the next few weeks. MacKenzie has been the Acting Executive Director of the National Biodefense Science Board, which is the Federal Advisory Committee for the Assistant Secretary for Preparedness and Response, and is well-versed in the processes and requirements of the Federal Advisory Committee Act and is going to be really a great asset for us. So our thanks, and if you'd join me in thanking Mary Jo, you can go off mute to clap if you would like, and our welcome to MacKenzie Robertson.

**M**
Indeed, welcome.

**Farzad Mostashari – Office of the National Coordinator for Health Information Technology**
That is so much for the introduction. And moving on, I think the amount of work that we have, again, it just doesn't let up, but it is incredibly exciting and it's within sight, so much of what I had hoped for in terms of making a real concerted push on standards-based exchange in interoperability for Stage 2, a lot of it is in the proposal and I think that if we can pull this off, if we can make sure that the standards really do reflect the absolute best in our thinking in the country today of what is mature, what is adoptable, what is good enough to move forward on, we will have done the nation a great service. And really one of the most heartening aspects of this is that there seems to be near universal consensus about the need for us to be aggressive on moving forward on interoperability and exchange that is standards-based from all quarters, and it's really an exciting time.

I do want to also acknowledge our very own Sharon Terry, who has proposed a really terrific fitness response, a video response to our HealthyNewYearChallenge.gov. All of you are welcome to also put up your own. I think that the challenge period has closed, but there's nothing preventing anybody from posting a YouTube video for themselves of how they're using Health IT to live healthier. Sharon's is just terrific, I urge everyone to take a look at it, and Sharon has some very impressive triceps also. We will now go to our co-chairs for the remainder of the session.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**

Thank you, Farzad. On behalf of John Halamka and myself, we join in really praising and thanking Mary Jo Deering for terrific leadership, not missing a beat, and exceptional dedication, commitment and effectiveness in your work, and we welcome MacKenzie. Know that there's a high bar, but we also have heard that you are up to it and look forward to all of us working with you in your new role. So on behalf of the entire committee, thanks, Mary Jo, and welcome to MacKenzie.

Let's dispense with our first order of pro forma business. One of the things that never ceases to amaze me is how effective the ONC staff are in really synthesizing the activities of the committee into a really very coherent report and so I'd ask you for your approval of the minutes. Please let me know if there are any amendments, corrections, amplifications. Hearing none, then we will assume consensus on that and move forward with the work of today.

Let me just note before I turn to John Halamka to provide some introduction to all of the updates on all of the activities going on around the NPRM, as I know that it feels, at one level, like a bit of hiatus from our regularly scheduled programs, but indeed if you recall back to our January meeting we set out a work plan for the year that, again, would relay this quarter, particularly March into April anticipating the NPRM and our collective work in responding and supporting ONC and providing feedback to the Policy Committee to help that process come together. As you know, during this quarter as well Jim Walker has been doing a terrific job working with colleagues to launch a second approach to the Quality Measures standards, and I appreciate and applaud that work, and simultaneously we note a really nice convergence with the response to the NPRM and the work that was planned for the NwHIN Exchange refinement. Simultaneously, we have the thread of activities that has converged in response to the NPRM and the Vocabulary Taskforce, and terrific efforts of both Jamie Ferguson and Betsy Humphries. So we see a convergence of our standing agenda with our timely response to NPRM.

As you recall, we have the body of activity that we're also thinking about for the next quarter of the year and that includes continuing work on really the NwHIN portfolio activities, Direct and Exchange activities that create the set of tools collectively that allow the interoperable environment or ecosystem that Farzad just described, and what a terrific boon that will be to moving forward all of the aspirations for interoperable health information. Query Health has moved from concept to something that's being realized in many threads of activities that I note that each of you are involved in, it's just tremendously gratifying to see the terrific concept come to life, and indeed there will be work and support that are needed that help in building out the query capability as well.

One of the areas that we have known that we were going to work toward was really the area of radiology standards, and it's really in the next quarter we need to really converge and convene a set of activities to make sure that the aspirations for the transport, the appropriate private, secure transport of images also becomes a part of interoperability of health information that's necessary for both better care and better health, and look forward to that work as well. Doug has been leading us through an evolution of the S&I framework and really also I would hope that the committee members share a sense of pride and satisfaction in ONC and Farzad and Doug and team's leadership in instantiating vehicles to take these various threads of activities and help to assure that they weave together into a fabric that leads to the interoperability that's important to the use cases, which now can be expressed and aspire to being very real world-like, not more laboratory like. And that of course will require the continuing evolution of not only our work and the standards support, but really the continuing stewardship and duration of these sorts of products to keep that ecosystem as healthy and effective as possible.

Further out, in the third quarter of the year further elaboration of clinical models, more support for consumer mediated information exchange, all sorts of activities that we'll be tackling, and as we get into the final quarter of the year public health, data portability, conformance testing, all of these things are things that we put on our docket and agenda, but there are a number of things that really fall into sharp focus as we complete a set of tasks related to the immediate requirement for response to the federal rule making process. So I appreciate your continuing work and attention to the standing portfolio of activities, but also appreciate both the urgent response and the interactivity of that urgent response to the rule making process with our continuing portfolio of activities.

I want to acknowledge and thank John Halamka for his terrific leadership. It just never ceases to amaze me how endless his energy seems, and how effective he is in tying together the threads of the different activities with Mary Jo and the rest of the team, very tightly engaged in all the calls and the initial teeing up of both the questions and plans for each of the response areas from whom we'll hear an update in the next few minutes. So let me use that by way of a segue, with an introduction to John Halamka for introducing the threads of the updates this morning. John?

**John Halamka – Harvard Medical School – Chief Information Officer**
Great. Thanks so much, Jon. You summarized it extraordinarily well, as you look at the first quarter, which is drawing to a close, and the work ahead in the second quarter, we are on track. Our first quarter's work really is focusing on the NPRM and making sure that it is polished. It's poetry, but there's still a bit of ambiguity and a bit of polish to do, which we'll talk about today, and I'll go through that in a moment. And as, Jon, you mentioned, we continue to work on quality measurement standards, the NwHIN Exchange refinement and vocabulary sets and vocabulary mapping, just as we said we would, but we're also looking to the future and teeing up the NwHIN portfolio review, the Query Health review.

As we'll talk about today, and we talked yesterday with Doug, we'll make sure the radiology standards domain experts are added to our clinical operations committee so that they can begin a taskforce analyzing radiology standards and ensure that as we go forward into April we'll begin some conversations about governance and where the S&I framework does a great job, but where other avenues and tools are necessary for dealing with either those standards that are highly mature and adopted, or those that are very speculative. And how do we ensure that ongoing there are processes by which we get standards of harmonization of all of the various gaps that we still have, because our work is not yet done, and lest we all rest on our laurels and believe that we have made complete progress, the answer is good progress, but there's still much to do.

So reflecting on the NPRM review, Jon, as you said, each of our workgroups is taking a deep dive into the NPRM on standards and certification and asking where are there ambiguities in the language, where do we need to fill gaps. So on the Implementation Workgroup side there's a huge amount of attention, you'll see, paid to making sure that we have clinically relevant tests around each of the certification criteria. The Stage 1 NPRM was very well done and very well written, but I think those of us in the field found that sometimes the tests, although technically valid, may not actually have tested real world scenarios of how physicians actually do their work. So now that we have the Implementation Workgroup and a little bit more time for review, we're really getting that real world input, and you'll see quite a lot of granular detail as they review the certification steps, the certification criteria.

The Clinical Operations Workgroup, also with its vocabulary taskforce, has spent a fair amount of time thinking about where there are gaps in content and vocabulary standards and also paid a little attention to transport, even though transport is much of the domain of what Dixie Baker's group does. And so, for example, on the vocabulary side how do we include appropriate allergy nomenclature for medications, substances that are non-medications, foods, environmental allergies, and making sure that we have a parsimonious set of data codes that can be used in interoperable data exchange to represent allergy, how do we ensure that ePrescribing of discharge medications flows to internal as well as external pharmacies, how do we ensure that the transport architectures that we need to do all of this are as flexible as we need to ensure that the various kinds of organizational architectures are supported. So you'll hear from Jamie on a number of these topics, which we've begun a discussion in detail and have another meeting to talk about in the upcoming weeks.

On Clinical Quality, as Jon has said, it's really ensuring that we have non-ambiguous eMeasures, thinking about what are the data models that we employ to ensure that EHR data elements that are used in practice are those that are reflected in quality measurement. And a simple example, I know, Jim Walker, you and I haven't talked about this, but in my recent work with the MITRE folks on ... we recognize that there's ambiguity in quality measures when you say you will include all patients less than or equal to 80 years old in this quality measure, is that 80 and zero days, or 80 and 364 days? And so what we found in our analysis system in the Meaningful Use Stage 1 measures is that each implementer could interpret the

language differently resulting in different numerators and denominators, and we want to ensure, as we go forward with the quality measurement, that we express in non-ambiguous ways those rules that eventually can be simply given to an EHR in a more general fashion without having to be pre-computed or pre-programmed into the code of a version of EHR, so lots of work going on in Clinical Quality.

Then finally, the folks from the Privacy and Security Workgroup have been extraordinarily busy at looking at the NPRM, of course on the security side, but also on the transport side, and such things as we do not specifically state that a patient accessing their own records to view them could use TLS, and recognize that as you go to eBanking sites you're doing HTTPS, you're using TLS to view your bank account data, and it's certainly true that Direct is a very important set of standards and will be used for EHR TO EHR, EHR to Public Health, and EHR to PHR transmissions, especially the non-tethered PHRs. But our tethered PHRs that are part of EHRs are very likely to offer portals that are TLS-based, so there needs to be some real clarity as to when TLS is appropriate and with Direct itself what is required, what is optional, must you implement both S/MIME SMTP and XDR, what is the role of SOAP in a non-XDR implementation guide, because you'll see there's some ambiguity between certain parts of the NPRM, where XDR is highlighted in one area and SOAP is mentioned as an option in another area.

You'll hear a lot of details from Dixie, and of course we have now convened our Consumer Engagement Power Team, which will ensure that especially as we talk about view, download, and transmit that we have clarity as to what is the workflow that a consumer will want and use and that we have the right standards enumerated to support that. The last 30 days has actually been a whirlwind of review with many, many calls and in the next 30 days we will wrap all that up and we will get our reports to ONC. So with that, I look forward to hearing the details from our co-chairs today.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
John, thank you very much for those terrific comments, and I join you in looking forward to walking through all of the updates from all of the co-chairs and appreciate their work. Let's start by transitioning to Doug Fridsma for his updates from ONC broadly ... containing the metaphor for the various threads weaving together really helping to set the context into which all subsequent presentations and activities will fall.

**Doug Fridsma – Office of the National Coordinator for Health Information Technology – Director, Office of Standards & Interoperability**
Great, thank you, Jon and John, and the rest of the committee. You guys have laid out a very, very nice set of activities that go back to our initial planning that we did a few months ago, and I think John is right, over the course of the last 30 days there's been a tremendous amount of activity. Today what I'd like to do is focus on just a few items that are currently in discussion, and then have some time sensitivity to them that are related primarily to the NPRM. I think it's also important, before I dive into some of the discussions, to just let people know some of the other activity, and certainly as we get through the review of the NPRM we'll be able to have some additional discussion about those activities as well.

One of the things that we are working on is we've identified a laboratory results interface standard through the Standards and Interoperability framework, and that was work that leveraged some of the implementation specifications from HITSP, as well as the expertise that we got from the California Healthcare Foundation and the work that they did on ELINCS. Going forward, the CHDF is working on developing a laboratory orders interface, and so one of the things that I would like to bring to the committee here soon is just an update on some of those discussions and the good work that CHCF is doing. Our hope is that we can, as we did before with the laboratory results interface, merge or create a specification that's going to be suitable to support not only the results part of this, but also the ordering piece, and that includes the need to make sure that we've got ways of describing the tests and the ways that you might order them. I think Jon and John have also described some of the work that needs to happen with regard to quality measures and clinical decision support, those are two sides of the same coin, and getting the standards and the specifications that are unambiguous and are computable will

make it easier for people to implement correctly the quality measures and turn those into clinical decision support if necessary for ... .

A whole lot of other activities that are ongoing; we're working with our federal partners to help us with some of the RESTful approaches to secure information exchange and to provide some pilots for a TLS approach, and we'll be letting folks know a little bit more about those activities as those become refined and we have a little bit more direction there. We're working very closely with Joy Pritts in the Privacy and Security group that she's collected to make sure that we've got the certificates and the trust and security infrastructure in place so that Direct and Exchange can be successful as we move into the next stage. So we look forward to having additional discussions about that as well as we go forward; lots of things that are going on. Let's go to the next slide.

I think the main thing that I do want to get a little bit of discussion today regarding is around consolidated CDA. It's the underpinning foundation of the ways in which we are going to, we hope, support transitions of care. And I think it's important, and this slide is perhaps a little bit difficult to look at unless you blow it up on your screen, but I think it's important to recognize what consolidated CDA tried to do and what some of the options that we have with describing the standards and the specifications that we need to follow to achieve interoperability. For those that are not tightly linked to the consolidated CDA, or haven't been following all of the calls and the like that have been going on, I think the thing that's important to understand, and I'm going to refer to the diagram on the right here, is that the consolidated CDA, in addition to cleaning up some of the implementation specifications and trying to make it clearer and less ambiguous for people to implement, it basically creates a way of assembling the pieces that you need to be able to achieve a standardized way of sharing clinical information.

And so at the very bottom of that diagram it talks about things like allergy status observation and allergy reaction observation and allergy severity observation, and those three things are elements that would help describe an allergy. So you might say that somebody got penicillin and they developed a rash that was mild, or you could say somebody had received penicillin and began having trouble breathing and had a severe reaction that required them to go to the hospital. Those things are collected, those individual elements are collected into what's called an allergy observation, and that becomes part of an allergy section level template. So somebody may have multiple allergies that are those observations, each of those observations are composed of a series of elements like what's the name of the medication, what was the kind of reaction, and what was the severity, and that shows up in a template at a section level.

So the consolidated CDA takes these individual observations, or these individual little pieces of information, and it puts them into logical sections that would make sense from a clinical perspective, and so the sections then have allergies and medications and maybe hospital discharge medications or postoperative diagnoses and a whole series of different kinds of templates at a section level that are described as unambiguously as they can be. Then through the process of transitions of care and some of the consolidated CDA work, those section level templates are assembled to support different kinds of transitions, or different kinds of documents, so a continuity of care record might pick an allergy section and it might include some other sections, but it wouldn't necessarily include a hospital discharge medication if that wasn't part of that continuity of care. A discharge summary, on the other hand, might include the hospital discharge medications and might include some diagnoses of procedures, might include some medications as well, and so what the consolidated CDA standard has tried to do is to take individual data and collect that into logical things like describing what an allergy might be, putting all those allergy bits of information into a section, and then determining which are the relevant sections to include in a document that would allow us to exchange information.

If we go to the next slide, so, just as an example, some of the document templates that we have, the continuity of care document has eight sections. It includes medications administered, plan of care, instructions, vital signs, social history, history of the past illness, present illness, medical equipment, those sorts of things. It has about eight sections associated with it, but a discharge summary and a consultation note includes a lot more information and they're not exactly the same. They have some different pieces to it. Now, all of these documents include header information, which includes what the encounter is and information about the patient and the provider and those sorts of things, and so when we think about how

we get to interoperability, obviously the more specific and unambiguous we can be about what's required to be able to support information exchange, the more likely we're going to get to interoperable exchange. Of course the downside to that is that if you've got some unique characteristic about your hospital or about the consults or the like, sometimes it can be hard unless we think very, very flexibly about adding additional information how to manage that, the tradeoff between expressivity, the ability to say anything you want, and standards that would allow us to get to interoperability is going to be attention that this committee will face as we go through.

Go to the next slide, so when we look at the 2014 edition of the consolidated CDA we've really gotten some clarity on the requirements which we believe is going to reduce the cost of implementation and have less errors, but I think it's important to recognize that it's not going to be zero errors. We have done our very best to create these specifications, but clearly there are going to be things that we miss, there are going to be things that need to be more refined, there are things that maybe need to have more flexibility in them, and so I think it's going to be important for us to take a look at the standard. And one of the challenges that we have right now is that the current consolidated CDA standard referred back to the consolidated CDA sections, but it didn't refer back to the transitions of care. A lot of that just had to do with timing, we had done a lot of work subsequent to the time that we had to lockdown the regulations and make sure that we could refer to them, but I think it's really important for us to think through whether or not we want to have sections and entries as a way to describe a standard, which may give us more flexibility, may give us a bit more optionality, but may make it harder for us to get to interoperability, versus leveraging the work of the transitions of care around documents that may say of all the sections that you need these are the ones that you need, it needs to look like this, and these are the kinds of options that you have or may not have with regard to this.

So I think it's important as we look through and review this to try to figure out strategically what's the right level in which for us to specify a standard and understand the trade-offs between having something that refers to lower level elements and say you need eight sections to describe transitions of care for continuity of care, for example, or referring to something like the transitions of care continuity of care document, is what we want to refer to. I'd just lay that out for those that are thinking through what the possibilities might be as well. I have one more slide and then I can probably turn it over to have some additional discussion.

This is an update on a somewhat separate and orthogonal task, but I think it's important for us to at least begin the process now, because if this is directionally aligned with where the HIT Standards Committee is, I think it will be helpful and it will give us an opportunity with ONC to continue to move forward with things. But this goes back to the Accountable Care Act and in there was a section called "Section 1561" that specifically called out the HIT Standards Committee, and the HIT Standards Committee was charged with identifying the standards that would help support health insurance exchanges. Now, of course in that legislation they gave us, I think, something like 120 days to go from zero to 40 fleshed out standards, and we did get some draft standards together that I think was very, very good with regard to the working group that we had. We had some support from both ONC and MITRE and some of our contractors, and we were able to meet the deadline with them.

I think the thing that's important as we think about this going forward is that CMS right now is implementing the federal insurance exchange, and they're using the HIT standards that were recommended as a guideline, but I think what's important to note is that they're using it as a guideline, they aren't necessarily following them specifically, in the sense that these were standards that were identified to the HIT Standards Committee, they were never really fully tested or implemented, and I think we are now, with CMS, having an opportunity to take a look at this. We've been in discussions with CMS and coordinating around these activities, but there are, like it seems everything in the Accountable Care Act, really very, very aggressive timelines to be able to develop the health insurance exchanges and have them ready for folks when the legislation becomes active and we've got people looking for insurance over the insurance exchange.

Now, as you know, those of you who are participating in some of the state efforts know that there are also state exchanges, and for those states that are choosing not to develop their own insurance exchange

they can use a federal exchange. And so one of the challenges that we have in this is that for all of these exchanges to be able to work together it's going to be important that we have appropriate standards, or at least consistency, in how people implement the interfaces between the various components. And so in working with CMS we've been asked to continue to work on 1561, in some sense to provide some visibility into the challenges that CMS is having with their implementation, and also to provide some visibility to the states and others to make sure that we're on the right track and not choosing approaches or standards that would make it difficult for these to interoperate. And so one of the things that I'm proposing is that we should form an HIT Standards Committee working group based around NIEM to help us evaluate how CMS is doing with implementing the standards that the HIT Standards Committee proposed, and provide a mechanism so that we have some transparency into the process and can provide some guidance and some support for the work that CMS is doing as well. So that's one of the things that I would like to see if we can get going, and if that's the case we can certainly work to get some volunteers who may wish to participate and put together a team that can help us assure that these insurance exchanges, both the state and the federal exchanges, have the ability to share information with regard to meeting the requirements of the Accountable Care Act.

So with that, I'm going to stop. There are really just two things; one is NIEM work and the need, I think, for a working group; and the second is to open up a little bit of discussion about consolidated CDA and the approaches to specificity in the rule versus section versus document, and what's the best way for us to get both the flexibility that we need as well as making sure that we get to interoperability.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
Doug, thank you very much for a very provocative talk this morning. Your comments, I'd say, were provocative in the best sense, in that we have a number of cards in the air, and just I'd note as one editorialization, is that I'm excited about the convergence of use cases between the clinical context and the administrative context, so I look forward to our Standards Committee helping support you in whatever way and I look forward to some good discussion about how we best meet that need. We have four individuals who have raised their cards electronically, John Halamka to begin with, Leslie Hall, I believe has a comment from a patient perspective on use cases that applied, and then Arien Malec and Wes Rishel I also have in queue so far. Let me turn to John Halamka to begin with.

**John Halamka – Harvard Medical School – Chief Information Officer**
Great, Doug, thanks for a terrific presentation. My question on the scope of consolidated CDA, so there's been a lot of debate over the last couple of weeks as to various use cases by which clinical summary transmission can be used. I'll give you an example, so the folks at MITRE working on ... health trying to compute the meaningful use quality measures said well, we expected the summary documents to actually be a lifetime summary document, not an episode of care summary document. So, wait a minute, if a meaningful use quality measure says have you had a mammogram in the last year, simply getting a CCD as currently structured, which describes the episode of care you had with your dermatologist, doesn't in fact reflect anything longitudinal about your year's health experience. So one question, would consolidated CDA be more of a longitudinal summary rather than an episode summary? And related to that, as we started to look at how one might abstract the EHR data and send it to a professional registry, a quality repository, etc., what we're finding is that CCD is again not completely perfect because it's underspecified for the transmission of data of a summary nature from an EHR to a registry of any kind.

Then finally, as we started thinking about multiple patient reports that might be submitted for the purpose of a batch submission to a registry, and Jamie will talk about this, we're reflecting on are there standards out there that allow us to submit more than one patient's data in a construct at a time? So when you say consolidated CDA and the work ahead, is it episode-based, is it summary-based, is it conceivably useful for the submission of data from an EHR to a professional registry or quality measurement indices, and might there be the capacity to report on more than one individual in the context of a document?

**Doug Fridsma – Office of the National Coordinator for Health Information Technology – Director, Office of Standards & Interoperability**
So you just went right to the heart of this, didn't you? Those are all excellent questions, John. I'm not sure I can answer all of them. In fact, it's one of those things that we could, and this is probably

something that will require some ongoing discussion both within the consolidated CDA and the transitions of care activity. Let me just say a couple of things. The consolidated CDA project started before the transitions of care activities to start to clarify the section level template, and that once they began to get those things then the transitions of care team began assembling those sections into things that would support these document level templates that would support particular use cases.

I think there are a couple of things that I can say about the quality use case. I think it's important whenever we take a look at these standards, and whether you decide to reuse the consolidated CDA templates or whether you decide to come up with another standard it's important that we are careful not to overload a standard that has been used for one purpose to allow us to use that same standard for another purpose. The example I think has gone from some of the work in ... health and Cypress, certainly I think providing a standard way of exporting and importing into these analytic tools that will help us do quality assessment is important. The question is whether we use something like the CCD to do that knowing that what is actually required for quality measures often is highly stylized, and as you point out, sometimes that information is not contained within a single episode, but is available over a long period of time.

And so I think one of the things for us to consider is are there other ways that we can assemble these building blocks together, or even go back to the CDA standard from HL7 and look at things like QRDA, for example, that has the ability to put not only individual patient level but a row and column approach where each patient is a row for a bulk upload, if you will, or bulk assessment of quality measures, as well as providing some of those summary activities. So I think as we think about what I like to refer to as a longitudinal care summary, or a longitudinal care record, in which we want to be able to collect over time what that looks like, registry data and the ability to include multiple patients, it's important that we take a look at what our existing standards are and make sure that we're using the appropriate tool to solve the right problem. I think you raise really important issues. I'm not sure that consolidated CDA is necessarily at its current or certainly the transitions of care is necessarily the document that's going to get us there, but it may be that some of those section level templates or going back to some of the more elemental building blocks, is going to give us an approach that will be useful.

**John Halamka – Harvard Medical School – Chief Information Officer**
Great, thank you. I look forward to the work ahead now that we know the issues.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
Let's go on to Leslie Kelly Hall. Thanks, John, great question.

**Leslie Kelly Hall – Healthwise**
Thanks, Jon. Hi, Doug. Thank you for the overview. I have a question at the beginning of your presentation and then some for the end. In the beginning you mentioned the work that you were doing on lab results, and I wonder if that also included patient self-ordered or self-referred labs, which are legal in many states, and if the standard would accommodate the receipt of that patient self-ordered lab when deemed appropriate by the patient. That's the first question. And then the next question I have is about the suggestions on the insurance exchange, and I totally support the effort to harmonize those because I think that that's one of the first areas where we actually have patient generated data in the insurance exchange that putting in a good deal of information about patient demographics and some family history, some health history, as well as obviously the insurance information, so perhaps we can learn from that and/or have them incorporate the standards we've already discussed with regard to patient demographics, vital signs, smoking status, height and weight, and so forth. Those are my two questions.

**Doug Fridsma – Office of the National Coordinator for Health Information Technology – Director, Office of Standards & Interoperability**
I think with regard to your first question, we are just getting underway, in fact, we're working right now with the team to try to establish the charter and what success looks like and what are the things that we'd like to be able to produce. So in some sense it's undifferentiated at this point. One would hope that regardless of what we do, whether we incorporate it in this phase or whether that shows up in a future stage, what's important is that we take that path of least regret, because I think you highlight correctly in

those two questions that we really need to make sure that as we move into this more patient-centric view of patients, and patients have ... cell phones and all sorts of other things that they can order tests and they can include them in the medical record, we need to make sure that that becomes one of the use cases that are considered and that we have the opportunity to be able to incorporate that information as well.

With regard to the NIEM work, your question number two, I don't know if it's specifically pulled out. The challenge that we have with the CMS work and NIEM is that in some sense there are going to be decisions that will need to be made that will require us to accelerate implementation before we get to standardization, and that's not necessarily bad. Obviously the best kinds of standards that we can adopt are those that are implemented, tested, and work, but I think the other thing that's important is that when we do those implementations and we do them quickly to make sure that we have the implementations up and ready, it's important that we have some transparency so that if there are issues like the path that you've chosen or the way that you're implementing that is going to make it more challenging for patients to engage or patients to be able to get access to that information, we want to raise those questions early, because that provides us an opportunity to do some mitigation and some risk management and to be able to help support this better. It is early in both of these processes and so I think getting that kind of engagement early will be helpful.

**Leslie Kelly Hall – Healthwise**
Thank you, Doug.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
Thanks. Let's go on to Arien.

**Arien Malec – RelayHealth – VP, Product Management**
Thank you. This is one of those odd places where I'm sitting facing myself, given the work that we did on transitions of care and consolidated CDA at ONC, but just a couple of perspectives to some of the questions you raised. First of all, relative to document versus section, this was one of the things that we actively discussed in the transitions of care work and felt, at least at the time, that it was important to standardize on the section level primarily because we recognized that there are a large number of kinds of transitions of care, some of which may be more or less specific, but that there was a policy interest in having at least a general subset of information that everybody could consume. So this is the Postelian principle of having a core set that everybody understands with the ability to add additional information over time. And what I think is a really compelling illustration of this is let's say that CMS has a future iteration of the MDS that's used in SNITs and let's say that CMS wants to use consolidated CDA as the scaffolding for that updated MDS, it would be useful if there was a core to that MDS that included medications, medication allergies, problems, and the like, that everybody could universally consume even if they didn't understand the specific updated MDS document. Now there's going to be some information that will be lost in transit and in those cases it's useful to use the consolidated CDA's ability to render the entire document as an HTML view, but it's also, I think useful to be able to consume universally the medication list regardless of whether you understand the surrounding document.

And then relating to John's question on expanding the set of use cases, there's a real tension, and I just want to comment on that tension. We did the transition of care work explicitly and incredibly focused on transitions of care, we chose three discharge, a closed loop referral and a complex coordinated transition to long term care, and there are a large number of additional use cases like quality reporting, like creation of an aggregated summary that incorporates information from multiple participants where you get into things like versioning, and we just try to solve, in the transition of care work, the core transition of care information. But there's a tendency and a tension when, and we saw this with CCD, when everybody can support CCD that's your hammer and you look for the nail interface, and you try to use CCD to do things that it wasn't designed for, and it's a little frustrating, but gosh, it's the only thing that you have access to. So I think we need to recognize that even if we're centered around transition of care, lots of people are going to try to use that and extend it in ways that weren't anticipated, and if it's designed right that can actually be, I think, useful. So that's what we were trying to get at was designing around a core of

information that everybody could universally understand but then maintaining some flexibility and upward compatibility, if you were, for more advanced use cases.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
Doug, I'm going to turn to you for any comments.

**Doug Fridsma – Office of the National Coordinator for Health Information Technology – Director, Office of Standards & Interoperability**
I think that those are all valid points. I think we've got a lot of cards up, so I don't really have anything to add with Arien's summary there.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
Okay, I appreciate those comments, Arien. Let's go to Wes.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**
Thanks. I just want it noted for the minutes that mine wasn't the first card in the air. Doug, I have a couple of pretty quick questions and then a fairly long one. Here's the first quick question. The NPRM specifies the draft of the consolidated CDA that was published in September. HL7 has done a lot of work since then and that work would be described, I think, in many respects as cleanup correcting errors that were detected during a ballot process, which is the normal flow of what happens during ballot processes. Is it going to be possible that the final rule could specify a more up to date version of the document, or are we, by the rules of NPRMs, are we now locked into the September document?

**Doug Fridsma – ONC – Director, Office of Standards & Interoperability**
That's an easy question. We can update that based on comments and based on work that has happened since that time. The only thing that Steve Posnack really needs with all of this is he needs to be able to incorporate by reference, so what that means is that having gone through the HL7 ballot cycle and being able to actually present something that you can point to that is persistent is really what we need. And so part of the challenge that we have is that if there are issues that come up between now and when the final rule occurs and we identify them early, getting through an HL7 ballot cycle, even if it's an off cycle ballot, may be important so that we can get the corporation by reference.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**
So we have a horse race here between an SDO's ballot cycle and the government's final rule cycle. That should be interesting. The other quick question before I get to the longer one is, in talking about the Health Information Exchange Workgroup you said based around NIEM. I assume that means based around the tooling that you're using in the S&I framework, is that right?

**Doug Fridsma – Office of the National Coordinator for Health Information Technology – Director, Office of Standards & Interoperability**
Well, I guess when it comes to the NIEM and the NIEM processes, this is something that has been used across the federal government for agency to agency standardization, and there are a suite of tools that are available for that. ONC has the responsibility for the health domain within the NIEM core, if you will, and the ACF, the Agency for Children and Families, has responsibility for the human services side of the world. So those two agencies, ONC and ACF, were working on shared governance that will allow us to accommodate the kinds of intra-agency exchanges that might be required. There are tools that the NIEM PMO have that we can use, and there are tools within the S&I framework that we can use as well. I think one of the things, though, that's important to note is that in large part the NIEM work, or the standards and implementation work that CMS is doing, is really focused, if you have to balance the two, it's focused more on implementation than it is on the standards process. And so in large part what we're trying to do is to work with CMS making sure that we trade off the standards versus expediency and to provide some degree of insight into the choices that are being made so that if we need to say this is the interface that CMS has developed, we need to take that and harden it and make it a standard so that the states can also use that same approach. That's really where the NIEM working group can provide us some guidance about which direction or how to proceed.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**

Thanks. I have two things that are more in the nature of comments than questions. Following on what Arien described, and he was following on what Doug described, I think it's important to recognize that in all senses except the strict rules of grammar, consolidated CDA is a plural phrase. It is intended to describe a set of standard documents, each of which are built using building blocks from templates that are contained in the lower levels of that diagram, and those templates may be pieces of the total inventory of all the things that can be said in the header, they might include sections, and the sections might include individual data entry templates, and wherever possible an individual data entry template will be reused in multiple sections and wherever possible a section will be reused in multiple documents.

But if you ask a question, and this is my understanding and it's not as deep as some people, but if you ask the question is this document conformant to the CCDA, it must be one of the enumerated document types in the CCDA. You can't just arbitrarily throw together some data entry templates and say that is a conformant CCDA document. Maybe you'd like to, maybe it's feasible, I don't know, but my understanding is that the hierarchy of levels of templates is what gives the context that allows you to understand what an individual medication means. Does it mean it's prescribed? Does it mean it was patient self-prescribed? Does it mean it was administered during a procedure? All of those things come not from the name of the medication, but from the way it's grouped into higher level templates.

Whenever we're working on standards we have two virtues that we'd like to support at the same time, even though they are somewhat conflicting. One is the ability to send as much as is possible, as much as what is available, and the other is to receive that data that I need in order to do what I'm going to do with the data. So when we generally think about sending a continuity of care document we think that the purpose is generally to inform the receiving physician about the patient and if we trace the CCD back to its history it was about the patient in the context of a prior encounter with the patient that wasn't, as I understand, meant to be simply what was done in that encounter, but it was not meant to be the entire history of the patient either.

We have situations where, for example, if we're sending data to a registry, if certain data isn't present in the appropriate context and expressed in exactly the right way, it can't be aggregated into the registry. That's a case where conformance to a very specific set of requirements is necessary. I bring this little tutorial up because it's important to recognize the way the NPRM is written. I think I, and a lot of people, would have assumed when it came to a discharge summary, or a transfer to a skilled nursing facility or something, that there would be a document type within the CCDA family that described that and that document type would be the thing that is required, that is written as a requirement in the regulation. That way there's the ability to address the assurance that the information that the receiver requires will be present in the document. Instead, a different approach that has a different set of virtues was adopted and that document is to say what is sent and therefore what's required to be received must be some document that is a member of the CCDA family and must have certain identified data elements in it, although those data elements are not specified with respect to the context that they go in, as they're not specified just as entry level templates, not as templates within a section.

The advantage of that, and it's a big advantage, is that there are many kinds of encounters that are most appropriately described with different documents, so a consultant note is different than a discharge summary, is different than a referral. But by making use of the commonality in the CCDA, we can allow the receiving system to receive all those kinds of documents and get whatever information is appropriate out of them, as opposed to having to specify and test each of the kinds of CCDA documents and then having nothing in place in terms of standardization as HL7 moves ahead and adds new document types in the future, so it's a big advantage. It leaves us, to a certain extent, telling the receiving systems, however, that they must receive all document types, that is, they must build their software so that instead of parsing top-down from the document type, it is able to go through any document type and pull out relevant pieces of data, many developers who are familiar with the CCDA will have done that, others may not. It's pretty easy to just look at the business of extracting data from any document in the CCDA family as an XPATH to pull data out of a very specific location. So in reviewing this and commenting back, we, and I would say the public in general and vendors in particular, developers in particular, need to

understand what is proposed, trade off the benefits of the current approach versus what might have been the more obvious approach, and decide.

Finally, I have repeatedly said, and I'll be very brief this time, that I believe it's very important that we do more than simply test and certify interfaces, that there be a very active set of processes for allowing testing prior to certification and for working on issues in a social environment that arises during that testing. I've been looking into that since the last meeting and I'm very pleased to see how much work is going on in that direction. I'm trying right now to gather that information and categorize it and publish it, and relate it what the actual requirements are. But overall it's very impressive what the industry is doing to pull together on these requirements.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
Thanks, Wes. I think we will circle around for any cards that are up, and I appreciate the thoughtful comments that you offered. Others that want to jump in on either of Doug's topics?

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
This is Dixie. I think I raised my hand.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
I'm sorry. I missed that. Please go ahead.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
I may not have. I just have a simple, or I think it certainly is straightforward question, on slide three, Doug, you talk about the header template. And there are only three sections there and none of those seem to be sections where one might put identity, provenance, and security metadata. I was wondering where those metadata would go in this consolidated CDA template section.

**Doug Fridsma – Office of the National Coordinator for Health Information Technology – Director, Office of Standards & Interoperability**
That's a good question. I'm not actually sure, and I will go back to the team and see if that includes all of the information. Obviously, the header information was previously reviewed and I think maybe this is a subtext for comment with regard to the metadata analysis that we had done, and it was the CDA R2 header that was included as part of that. So the question is, I don't know if this information is a template that fits within that larger CDA wrapper or if there's a specific header template that includes not just these three elements but some additional elements as well. I'll take that as a question to get back to you on.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Thank you.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
Doug, you may actually see anybody who's electronically raised their hand. Others, if you'd like to comment on this area please speak up.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Jon, would you mind reminding everybody to please mute their phones when they're typing?

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
We'll do that. Please take that as a reminder, all. Okay, well, Doug, just a terrific overview of the ... activities. I believe we owe you a response on a proposal to form a NIEM workgroup to help evaluate CMS success in implementing the standards. Unless there are any specific objections, we'll assume that we'd be delighted to support you, and perhaps John and I can work with you and MacKenzie in the interim to really develop an approach that integrates with the rest of the activity. So unless there are any objections, speak now, committee. Great, then, Doug, you have our complete support on that, and look forward to the ongoing work in this area as well as the more clinically related standards.

With that, let me turn to John Halamka. John, you have just been so absolutely terrific at being at virtually every phone conversation on each of the NPRM questions and planning activities, in fact, you joined a conversation yesterday, you and Jamie both, immediately after the Operations Vocabulary Taskforce. But let me actually then, John, turn to you and we'll go in the order that they're listed on the agenda and we'll work through all of the terrific work, all of the co-chairs' and committees' activities on responding to the NPRM. John?

**John Halamka – Harvard Medical School – Chief Information Officer**
I'm happy to do that. So as we begin this review we'll start with Liz Johnson and Cris Ross, who are going to ensure that we have *meaningful* certification criteria. I hate to use the word "meaningful" in that context, so we'll use meaningful with a small "m." So Liz and Cris, please go ahead.

**Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics**
Thank you. We'll go to the next slide, please. The first thing I want to do is just thank all the folks that are on this list. I can tell you that the work that has been going on for multiple 2+ hour meetings is very reflective in the documents that we're going to share with you, so thank you to all of the members, the activity and the participation has been nothing short of phenomenal. I also want to recognize Carol Bean, who has been instrumental in providing us with the test procedures for review and so on. So again, the work together has resulted in a significant body of work we're presenting today and we'll go through that now, so if you can go to the next slide, please.

Today what we're going to do is we're going to provide you some general comments on the testing procedures, recognizing that this work began prior to the NPRMs being released, and so we attempted to consolidate both the previous work with some very early work on the NPRM, which will be followed up in conjunction with the rest of the workgroups going forward. We really did organize it into clinical work considerations, as well as measurement considerations. As both the John's have indicated, we think it's critical, and I think the Standards Committee thinks it's critical, that the test procedures clearly recognize that these applications are being used in clinical environments and need to be reflective of workflow in order for the functionality that the software vendors provide us will actually be usable in a meaningful way. We also provided you, we will not go through it today, a 31-page document where we went through measure by measure and provided extensive comments back to the testing procedures and back to Carol so that those comments could be incorporated in future development.

And then finally, and we're just beginning a work plan and we want to meet with the jobs, in fact have a meeting set up, to really talk about what's coming next from this group, certainly the completion of the comments on the testing procedure, and Dixie will talk about some work that her group is doing on that, as well as we've done some additional work that's not yet reflected in the grid. And then we want to complete our meaningful use certification criteria comments related to NPRM, again, working in coordination and consolidation with the rest of the groups. We really feel like it's critical that some clinical scenarios be developed and utilized in testing, and so pending chairs' approval we'd like to step up for that work, and then beginning to identify activities to gain public insight into the implementation opportunities that are going to be presented by Meaningful Use Stage 2 and what can we do as a workgroup and a committee to provide guidance standards and tools to ensure that we have successful implementations going forward.

Now I'll move to the next slide, I'll move into specifically some of the high level comments, and again I would refer you to the 31 pages of comments that have been provided, and these are some of the high level recommendations or comments that were coming from, and they really are just comments. Carol and her group have been, along with Kevin Brady from NIST, have been extremely receptive to what we've offered to them. The first one is really related to CPOE, but a general comment as well, and that is we really need workflow scenarios and we need to know what's going to be countable, and it needs to be context in relationship to either the eligible hospital or the eligible provider, and John, on several occasions, as well as others, Joe Heyman in our group, have pointed out that we asked for, and this was certainly addressed in the new NPRM, for us to provide tests around activities that did not occur in our normal workflow, and I think that's been addressed well, but we wanted to point out and continue toward that same trend. Then we also, as we're designing those workflows, suggest that we design workflows

that don't test a single measure. If we are capable of providing a clinical scenario that tests multiple pieces of measure that are comparable within that workflow that unfolds in a clinician's day, the workflow and the tests will be much more effective and applicable to the work that we do.

The next consideration that we ask for is that we be able to show where there is a non-answer, and we gave you a couple of specific examples. There are times when there is no problem or no medication allergy or no advanced directive, and so on, and so we need to be able to meet that need. And it also ought to be in conjunction with reducing physician burden or other clinician burden. For example, if we are able to acknowledge that a medication is part of medication reconciliation and also part of a medication list, can we find a way in testing to provide both pieces of testing in a single opportunity. So those are the first two. We'll move to the next page, please.

And again, we're continuing with workflow considerations, so you will see some ePrescribing workflow information here and later some additional information related to measurement. We believe that the procedure should be very explicit related to the prescription types, for example, dispensed as written and so on, and that we also might want to consider, and are testing procedures ... with the NPRM, are we routing to retail or mail order pharmacies and how are we testing for that. Back to the clinical scenarios, on the next one we really spend a great deal of time talking about notification and how do we notify the end user and is it tested for so that we know it's actually viable in a clinical setting. For example, does the test support all the ways we can notify, does it support that we need real time ... alerts as well as we're going to alert you later. And what I mean by that, for example, when a registered nurse enters an order for a physician the alert is going to be apparent at that time, but should be appropriately answered by a physician, and we need to deal with that. And then be sure that we clearly define what the user is, what the roles are at the alert levels, again, playing into the same theme of notification. So it becomes critical at the clinical scenarios, again, and those that we test for are relevant in our clinical environments. From the perspective of CDS rule information, we want to be sure that there are viable options to be able to link the decision support rule with where the information came from and are we testing for that. So as an alert or CDS process takes place do we know where that clinical decision support is coming from. So we'll move to the next slide, please.

We want to work on, again, with the CDS, and we went through a great deal of this and I won't go through all of the things that we've provided, even in the update, but we would like to see that when we're doing clinical decision support that we look at both combinations and single testing capabilities. So, for example, on demographics we may want to test for the availability of demographics but then are there going to be certain combinations that we should also test for, for example, age and gender and meds in a specific clinical decision scenario. That is both a workflow and a measurement comment, but one we think will be critical going forward.

We noticed in the next comment that although the meaningful use NPRM did not call for patient communication preference, it was called for in the NPRM related to standards, so we want to be sure, again, that we have a way of documenting patient communication, and this particular example is not available. So can we both document what the patient communication request is, as well as the fact that it's not there. Then we want test procedures that can verify the capacity to report in various formats, so if it's appropriate to produce both a paper and electronic copy are we testing for that, and what is the clinical scenario that will surround that.

Moving on to the next set of requirements, our recommendations, we want to be sure that the test allows us to do a clinical reconciliation, and an example that we provided you was around if you look at the NPRM and the meaningful use, both of those NPRMs, you will notice that we're expected to be able to replace new data with old, but we still need a chain of custody so that we can recognize from a timeline perspective when was that data updated, so how are we going to test for that and make it relevant. Then we also need a way, and this was another long discussion that we had, about the ability to mark information that is valid or invalid, and it's not a matter of invalid in the past but invalid today, so if you have an advanced directive, for example, that was valid obviously at the time that you put it into your system but it's been replaced, both need to be maintained but it needs to be clear from a care perspective which is the current advanced directive.

As we look at test procedures it is evident that one of the standards recommendations ... the NPRM is that we have human readable formats and so we need tests for that. Then we need to be sure that we test and differentiate between manual and automated processes. In looking at the EMR it's been suggested by the NPRM that we would use assisted technology. We're not clear yet on what that means and we need to get more clarification, and you'll see that in further comments when we consolidate with others, but we also need to be sure that more than just assisted technology, can that be justified by the fact that we have a confirmatory action by the end user so that we are ensuring it's not just assisted technology but we're keeping clinical judgment in the mix so that we're doing the best thing for the patient.

I'll go on to the next slide, and we know we're coming at you with a lot of information, and now we're going to move into, we've talked about some of the workflow and I said there are many, many others reflected in our documents, but now we're going to talk more specifically about measurement considerations. And when we looked at public health reporting we really believe that it falls into both we need scenarios that prove that public health reporting works, but we also need to make sure that the submission process is clear with the testing date example, so for example, one of the discussions we had was there is a significant difference between state registries and can we facilitate success in meaningful use by recognizing those differences. Do we have the technical improvements that are going to be required so that we can do public health lab reporting? Is there a conformance testing tool so that we can look at syndromic surveillance? It's a possibility that we're recommending that we should align with the Centers for Disease Control and Prevention and look at should there be more data elements than were actually tested for in Stage 1?

Moving to the next slide, as I said earlier, we had recommendations related to ePrescribing. Here are some recommendations around the measurements. From our group there was a recommendation about NCPDP 10.6 and yesterday I joined with Jamie's group to talk about this same recommendation and there was further conversation, so I'll leave that to Jamie, and again we'll make sure that when we take our comments back to ONC that we have a consolidated view on this. We also wanted to consider the controlled substance issue, is that something we should be looking at moving forward, and it certainly will require clinical workflow because those substances will not be handled in the same way we handle other ePrescribing methodology.

The next thing we looked at is really around measuring events. As we dove into the NPRM we recognized that in many instances we really were looking for what was being required, at least currently, was audit evidence of measurement, and so here were some examples where we would want to show audit evidence, not necessarily outcomes, so tracking overrides, identifying numbers of alerts and so on. Then obviously we found a number of places, as I'm sure others have, where we feel like there's need for clearer definitions, and we shared that with Carol and her group, as well as we will respond to that for the NPRM.

Moving to the next slide, we really wanted to be sure that testing procedures would verify that the EHR has a list of possible input data without limiting the structure. So we really want to be sure that we don't describe the process, that we really allow there to be freedom in that area, flexibility, but we can prove it's been done so that we can determine that certification is appropriate to the vendor. We need to be sure that the testing procedures allow both positive and negative qualifications for the measure, including numerator and denominator, and again, as we looked at the new NPRM we saw significant forward progress in this area, but the examples we gave I think makes the request very clear. It makes a difference whether we're looking at patients without lab orders, or patients with lab orders, but those were not placed by CPOE, a patient with a problem or a patient with a problem but not recorded on the problem list. So again we need to both do the measurement and the clinical scenario component so that we're sure that what we're testing is usable in a clinical setting.

Moving on to the next slide, we really want to be sure that the EHR software calculates the numerators and denominators, it calculates the measure of the percentages without manual intervention and that's certainly something that, again, I think we've made significant progress with the new NPRM. Then we

want to be sure that it's very clear what is being measured for the numerator and the denominator perspective. We want to be sure that the activities that are being reported during the time, how will they be measured, is it lab orders versus lab results, a lot of discussion around the eligible providers in this area and how is that going to work. We think it's clear, but we want to continue to question so that we're sure as we move forward and we inform not only ONC but the public on what's expected we're all together on that validation and then ... for the final rule. We want to be sure that if there are necessary pre-conditions for an acceptable level of data that it's been defined, is zero of one enough, is one of one enough, or should the data set be larger?

Then finally, we want to be sure that it's appropriate that the test procedures verify the existence of the time stamp to make sure that the information is up to date. We gave the example of the problem list so that it's timely in nature, and we want to be sure that we clearly recognize that measurement data may be coming from multiple source tables and articulate how that measurement should be compiled. For example, if patient access is required, we know it may come from an HIE, a portal, an ED, a clinical system, and can we use the combination of those, where does the information originate, what are our sources, and so on. And then finally, again, the time context, we need to be real clear on the time context in measuring both the numerator and the denominator.

Jon and John, we recognize that we have given the Standards Committee a tremendous amount of input on the comments back on testing procedures. We also provided, again, a 31 page document that Carol and Kevin have been intimately involved in, and that's where we are today. We're looking forward to several meetings we have coming up to add additional information to respond very specifically back to the standards NPRM.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
Great. Thanks so much. Your offer to develop clinical scenarios to be utilized as part of testing would never be refused. More work, great. For example, one of the areas you highlight is to ensure that there is a scenario and a workflow around EMAR so that the right medication and the right dose is given to the right patient at the right time with the right administration method. Today the NPRM, again, very well written, certainly much more clinically relevant, much more meaningful testing procedures, but on EMAR I think we lack that, that is, these five rights are not explicitly called out in a testing methodology that would enable us to use a variety of technologies, whether that's bar codes, RFIDs, pictures of the patient, facial recognition, so many technologies are possible, so how do we provide a meaningful testing procedure that gets us to ensure those five rights are incorporated into the functionality of the complete or the modular EHRs, so we certainly look forward to your work in that regard.

**Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics**
Great.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
I believe, at least the queue that I'm looking at, that I only have one immediate comment and that is from Leslie Kelly Hall, who has a question for Liz.

**Leslie Kelly Hall – Healthwise**
Thanks, Jon. Liz, I had some questions about accommodating future thinking and also specifically around the clinical decision support testing that you mentioned, accommodating both the idea of a real time decision support and an asynchronous decision support, if there was any consideration for that as decision support could be used as needed information, telemetry, labs and so forth, come to be. But it also could be used when there's other complications going on with other physicians or the patients themselves, so that the ability to accommodate both synchronous and asynchronous clinical decision support or shared decision making such as a comment or question, to see if that was considered and then on future thinking as we consider testing for areas where there is a logical place for patient inclusion, have we started to think about how that might modify our testing and implementation today.

**Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics**

Excellent questions. I think on the first one we did talk about asynchronous notification, and I think your comments can further clarify that comment back to the testing procedures, so that's appropriate. And I think that even the use of the word "asynchronous" further clarifies what it is that we're interested in doing. We hadn't talked a great deal about patient inclusion in this round, but I think it's a very appropriate thing to think about, and as we work together on patient empowerment and then back to the Implementation Workgroup, we will take that back and talk with the workgroup about where can that be included, is it something that would be appropriate in this round of thinking, is it more related to test procedures, or is it more related to other types of activities around implementation. So thank you for that comment.

**Leslie Kelly Hall – Healthwise**
Thanks, Liz.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
Other comments or questions for Liz or Cris? Wow, I think you just dazzled them.

**Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics**
Yes, or overwhelmed. We'll go with dazzled, that's good.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
I really believe the framework that you have created is so comprehensive and so logical that it just has great face validity. The service that you're doing to refine the NPRM is substantial, and as we've all talked about and you highlighted that we didn't have the luxury of time in the Stage 1 activities to give this level of rigor and the clinical relevance, the workflow analysis, the validation by multi-stakeholder groups that what we were testing was really something that a clinician would encounter in their day-to-day use of a standard EHR, so this is great.

**Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics**
Thank you.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
Well, with no further comments then I'll let us move forward to Jamie Ferguson for the Clinical Operations Workgroup and the Vocabulary Taskforce updates.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**
Great. Thanks very much. I don't have slides to present here. We're still in the process of drafting and refining the written comments, but I'm happy to talk through the areas that we plan to comment on as a result of both vocabulary, and yesterday we had a very productive Clinical Operations Workgroup call, so I also want to thank everyone who's participated in those calls, both ONC staff and the workgroup members. I think it's been very productive.

I think the first thing that I want to say is how much the workgroup members appreciate the clarity and frankly the improvement in the drafting of the rules in terms of readability, how well it can be understood, and it's not that we don't have questions, but we really appreciate the effort that went into the record of the NPRM. The areas where we plan to develop specific comments, the first one I'll mention is on the encounter diagnosis data element, where ICD is specified and a question of whether the intent of that was really for the billing use case or to capture clinical diagnosis, and what we heard from ONC staff was that in general where the diagnosis is mentioned in the NPRM it's intended to be used more in the clinical case, and so we feel that if the intent is clinical then really SNOMED should be used for the encounter diagnosis. But if the intent of the data element is for the billing and reporting use cases, then ICD would be appropriate. So that needs to be specified, but it's also possible to add a second field to specify both clinical diagnosis as well as the billing classification and so it might be useful to have both SNOMED and ICD.

That led into a discussion about the clinical friendliness of SNOMED for clinician documentation, and we heard that clinicians actually prefer SNOMED, but we also are considering commenting on the usability of

SNOMED for problem list information, problem list data entry, particularly in cases where the problem list may require post-coordination. And the way that that's handled in terms of physician input, we heard from different workgroup members about different approaches in terms of particular EHR systems that it all seemed to work equally well, but that's an area that could potentially be problematic, as opposed to the pre-coordinated concepts where the use of SNOMED is relatively easier.

As Liz mentioned, we did have a discussion on discharge prescribing in particular, in eligible hospitals. And so if the intent there is really for internal operations versus external interoperability, then HL7 is used, but if the intent is strictly for external interoperability, then obviously the NCPDP with the version notation that Liz mentioned is appropriate. And the question that we had really there was whether the standard was required for use in the meaningful use measure, because if the use of the standard is not required, then it's fine not to mention HL7. But if the use of the standard is required and discharge prescriptions are filled by the hospital pharmacy on the premises, then HL7 really must be listed in the regulation.

Moving on to allergy vocabulary, we had a couple of questions on the use of Uni, which we had previously recommended the unique ingredient identifiers in Uni RxNORM for medications and I think SNOMED for causative effect, but in the meantime Uni has been added to RxNORM, and so it's really a question of which identifier should be used for the same concept and so we feel that the RxNORM Rx ... identifier for the ingredient concept should be used as the identifier for allergies, so that really unifies things under RxNORM and that would be a change to the proposed rule. Just to emphasize, this would be using RxNORM generic codes only, not at the package level.

I think John mentioned that we did have a discussion on transmission protocols, and the feeling in clinical operations was that the rule should support both S/MIME SMTP and SOAP equally, in other words, both should be equally required for certification and leave it up to the particular use case and the implementer as to which protocol to use, whether to use the query response or the direct point-to-point. The other thing that I believe John also mentioned earlier was on groups of patients we found that there isn't a standard specified for groups or lists or panels of patients to be transmitted, but for example, in registry updates that may be required. So we had a discussion about the fact that HL7 version 2, or version 3, or CDA could be used for this purpose, and can be used for this purpose, but there isn't an implementation specification that we're aware of that essentially could send a batch of patients to the registry in that sort of an update that could also be applicable to adverse event reporting with groups of patients.

In terms of patient access to information, we had a discussion about the sufficiency of TLS as the transport for the portal scenario and so we think that that could be simplified and clarified in the rule, but we also felt that the consolidated CDA document family should be the appropriate family for downloads, as opposed to ASCII free types because the CCDA formats enable achieving goals of interoperability in addition to providing patients the ability to view and print and so forth with their information that's downloaded. Separately, we also had input from one clinical source that requested we consider adding country of birth, or country of origin, as a required demographic data element, noting that that could be more important than the race and ethnicity codes in some cases, and so that could apply to certain patient populations and certainly should be considered then.

We did discuss a couple of other items where we felt that we did not want to recommend particular standards, and that is for family history. I think it's an unclear result in terms of the search for appropriate and mature standards and also in terms of structured sig for ePrescribing we discussed that and felt that it would be premature that this could be potentially a future item. We did put a couple of things on the back burner for our next call, which also have been discussed here in the Implementation Workgroup and in the preparatory comments, and that has to do with the medication reconciliation and transitions of care and also the scope and use of the Info button in terms of clinical decision support. So those are things that we'll pick up on our next call in addition to the drafting and refining of the comments.

So with that summary, I'd love to take questions if there are any cards up.

**John Halamka – Harvard Medical School – Chief Information Officer**

Actually, Jamie, just one clarification, on the family history discussion what we did reflect on is there is this surgeon general tool and XML format that some had implemented successfully and it is mentioned in the NPRM, and so recognizing that family history is certainly important and certainly there have been multiple approaches from multiple SDOs, but it seems at the moment that the surgeon general's XML is that that is most widely deployed. And opening it up to other comments, I don't have any cards raised in my e-mail stack.

**M**
Jon?

**John Halamka – Harvard Medical School – Chief Information Officer**
Yes, please.

**Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief**
This is Nancy Orvis. I have my card up too, but it's not working somehow.

**John Halamka – Harvard Medical School – Chief Information Officer**
Go ahead, Nancy.

**Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief**
I had a question with the vocabulary group. Jamie, there's a lot of aspects of medication, and you mentioned a really important one on that the Uni codes we wanted to now use the RxNORM type for that. Is that going to also be true for the RxNORM code for the drug classifications?

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**
Yes. Basically we're trying to achieve parsimony in terms of the coding systems that we're using where possible, and since all these things now are in RxNORM, including the ingredient level of the drugs, that that means that we can use the Rx ... as the identifier for all of those concepts instead of the separate Uni or ... or other concept identifiers.

**Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief**
Okay, that's great. Has there been some comparable smoothing, if you would call it, for allergy information too? Are we going to address that in this phase?

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**
The purpose of using the Rx ... in this case is for the drug allergies and non-drug, or rather the ingredient level including the inactive ingredients.

**Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief**
Okay. What I think I would like to suggest, and I'd be willing to help work on that, is that we would have "modernization" slide or chart to show it used to be this but now we're going to be using this, because RxNORM has matured. Part of the reason that I say that is because some of us have been working on that standard for about six to eight years, and anything we can do to help educate our older folks who have been using RxNORM for about five years would be really helpful.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**
Sure. I think we can do that. That should be pretty easy. And essentially it really is the same recommendation as what we previously recommended in terms of using the unique ingredient identifiers, it's just that now that they're incorporated into RxNORM we can use the RxNORM identifier for the same thing.

**Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief**
And also just as another side part of that, when we were to address food and food allergies, about five years ago there had been an initial recommendation on foods as well, and is that another topic we're going to try and resolve for the final rules?

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**
I think that's a good topic to take up in a Vocabulary Taskforce call.

**Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief**
Great, okay.

**John Halamka – Harvard Medical School – Chief Information Officer**
To summarize the importance of the discussion that just happened, what we identified was that in the HITSP work and in multiple years, as you just described, of effort on allergy vocabularies we've talked about using NDC, RxNORM, Uni, NDFRT, SNOMED CT, all these variables, and now the maturity of RxNORM provides an elegant crosswalk of all these sub-vocabularies so that in fact you can simply use an RxNORM ... and have the benefit of the richness of Uni and of NDFRT inside RxNORM itself. So internal to your systems use whatever you want. It turns out Beth Israel Deaconess happens to use First Data Bank, and as long as you can take whatever internal codes you use for that medication, that ingredient, that non-medication, the food, the environmental allergy, and map it to some common vocabulary, so over the wire we have one consistent set of ..., then we will have true interoperability. And so as Jamie described, our effort in our call has been to figure out what's the parsimonious set of ..., and boy, RxNORM looks like it hits just about everything, but we hadn't specifically looked at food vocabularies. I'm not an expert on that one, so as you say, Jamie, future call.

Other comments? Was that Wes' voice I heard?

**Jim Walker – Geisinger Health Systems – Chief Health Information Officer**
It was Jim.

**John Halamka – Harvard Medical School – Chief Information Officer**
Oh, Jim, please, Jim.

**Jim Walker – Geisinger Health Systems – Chief Health Information Officer**
A few comments. One, I want to echo what I think Jamie was saying about SNOMED being the core clinical vocabulary. There are lots of organizations that don't have that clear, and I think we need to get it clear, get it clear in the NPRM, and then really communicate that effectively, that SNOMED is the language to do clinical work in and then to be able to translate to ICD when you need to drop a bill, I think would simplify and clarify a lot of organizations' approach to this, if that's what we're recommending.

A second thought, Jamie, about country of origin, I appreciate the clinical reality, but I think the construct is not clear. It might be country of origin but it may be not country of origin at all, the person might be born in the United States and spend 20 years in Nigeria, and so I think the construct is more some foreign place where someone lived that could shed light on their health and healthcare. And so I just urge us to think about really figuring out what it is we're trying to say before we codify it.

A similar kind of comment on the family history, specifically the attorney generals, there are elements of the family history that are highly specified and that are needed to compute clinical prediction rules, so what is the likelihood that a woman has the BRCA-1 or BRCA-2 gene and needs special counseling and potential interventions to prevent breast cancer. And what is the likelihood that the patient in front of me in the emergency department has chest pain because of coronary disease. And neither the surgeon general's family history, nor any other that I'm aware of uses those computable, highly specified elements of the family history, coronary disease in a first degree relative at age less than 55, for example. And it seems to me if we codify something that doesn't have that kind of specificity then we'll be asking people to document family history that has no predictive value, to put it, I think, not too strongly.

And then finally, John, your comment about First Data Bank makes me wonder if certification of those providers of drug information, to put it very crudely, wouldn't be something that would be worth talking about. I think many organizations had the experience that there are pervasive and relatively easy to fix problems with those information services, of which there are only three that I know of, that, if they could

be fixed would make it far easier for healthcare organizations to manage drug-drug interactions, allergies, a whole set of critically important issues much better.

**John Halamka – Harvard Medical School – Chief Information Officer**
And certainly that last point was very well said. I have heard the same sort of issues. I mean, not to mention any one vendor of any one product, but of those three vendors sometimes you say, oh well, they've had this long standing issue with the way they describe the dosing on this medication, it's never getting fixed, so by what means do we ensure usability of those underlying code sets if the end result has got to be a consistent RxNORM ... on the wire.

**Jim Walker – Geisinger Health Systems – Chief Health Information Officer**
Right.

**John Halamka – Harvard Medical School – Chief Information Officer**
Jim, just responding to one comment you made about the importance of SNOMED CT as the clinical facing vocabulary, Mary Jo, I will send you, there's a very fine article that was published last week written by Chris Chute, Stan Huff, Jamie Ferguson, Jim Walker, and myself that does evaluate the ICD-10, its clinical implications, the use of SNOMED and other alternatives and time frames and alignment with Meaningful Use Stage 2 and Stage 3 that may be of relevant reading to the committee.

**Farzad Mostashari – ONC – National Coordinator for Health Information Technology**
This is Farzad. Actually, if our folks can help send out a link to that, that would be great.

**John Halamka – Harvard Medical School – Chief Information Officer**
And it is now sent to Mary Jo, and that is the full text article, Mary Jo, in PDF that I've sent. So other comments? Jamie, any comments that you would make to Jim's –

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**
No, just I agree with Jim's comment that our intent was to clarify that SNOMED should be used for clinical diagnosis purposes in that particular area where that seems to be the intent of the proposed rule, but that it would be possible and perhaps desirable to add a second field for the billing classification.

**John Halamka – Harvard Medical School – Chief Information Officer**
Very reasonable.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**
David McCallie with a question.

**John Halamka – Harvard Medical School – Chief Information Officer**
Yes, David, please go ahead.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**
For Jamie, I dropped off the call for just a second so you may have already answered this and I missed it, but sometimes in order to match SNOMED codes with the granularity of an ICD-10 code in particular you would need to use post-coordinated SNOMED and your comments here are suggesting SNOMED for the standard clinical vocabulary, which I agree with. Does that include a standard approach to the post-coordination, or is that further than we've reached with the way we see SNOMED being used?

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**
I think that's further than we've reached right now. My thinking is that the workgroup had a discussion about the usability of systems where post-coordination was required for problem list documentation, but not in terms of specifically the mapping of post-coordinated concepts to ICDs. But that really in our previous comments from the vocabulary taskforce, our previous set of recommendations actually from the committee about having all of the vocabulary sources available from a single federal office or agency through a set of consolidated services, that standardized cross-map of whatever is going to be required,

which could include post-coordinated terms in mapping to ICD, should be provided. And so I think that might be useful to review and reinforce those comments, if that's what you're suggesting.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**
Yes, and I'm also concerned about the interoperability implications of post-coordinated SNOMED expression, how is that actually passed through CCD and can vendor systems parse it correctly? Post-coordination isn't open ended, you can have arbitrarily complex structures, and I suspect there are interoperability implications if we start assuming that they'll be captured but can't be passed around.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**
Yes, there is an HL7 guide for the use of SNOMED within CDA and we can certainly review that, but my recollection is that that does cover the recommended way of capturing those post-coordinated expressions in a consistent way, at least in CDA.

**David McCallie – Cerner Corporation – Vice President of Medical Informatics**
And that's good. I need to go review that myself, but I'm also concerned about the EHR's ability to actually deal with it correctly if it gets an open ended, complicated, post-coordinated expression. If we limit it to specific use cases like laterality, it's probably not a problem. But SNOMED itself doesn't have an automatic way to do that. You can keep nesting as deep as you want, I think.

**John Halamka – Harvard Medical School – Chief Information Officer**
Well, I see that we have two other cards that have just gone up, and that is Arien Malec and Wes Rishel. So, Arien, please go ahead.

**Arien Malec – RelayHealth – VP, Product Management**
Thank you. My hobby horse is allergies or intolerances to drug classes, and I was also, like David, away for just a second, so apologies if you already addressed this. But relative to your comment on the four significant manufacturers of drug databases, one of the issues with class terminology is that they're often used for multiple purposes, so for example, looking at common mechanisms of action versus common formulations or uses, for example, a topical dermatological agent versus a set of compounds with common mechanisms of action. And it occurs to me that a certification enforced, at least a minimal set of high value classes that are linked to significant allergies or intolerance would help the major drug database vendors at least get to some comment interoperable drug class list and that that creation of a short list could be a good way to get interoperability done. Anybody who's done class-based allergy interoperability knows that it's a real pain right now.

**John Halamka – Harvard Medical School – Chief Information Officer**
Right. And the only thing we said in your absence is that the NFRT being a more class oriented vocabulary is incorporated into RxNORM at this point. But it doesn't address the certification issue you've just raised, and, Jamie, I'm wondering if the Vocabulary Taskforce, can we make a recommendation as to the nature of what it is that these various proprietary vocabularies should be able to map to.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**
Yes, and there would have to be, again, from presumably the NLM or potentially another federal office, a publication of exactly the kind of a list that Arien is calling for, so there are certainly subsets that are available, but I don't know that there's a designation of a particular subset for this purpose that is now available or that could be done before the final rule.

**John Halamka – Harvard Medical School – Chief Information Officer**
Arien, did you have another comment?

**Arien Malec – RelayHealth – VP, Product Management**
No, just the notion that to the extent that there's well known and well documented allergies and interactions, if there's a short list that can be targeted, but if nowhere it exists, perhaps that should be a high priority research topic for NLM.

**John Halamka – Harvard Medical School – Chief Information Officer**
For example, what we have at BIDMC is the FDA black box list, and I'm happy to share that in the public domain, and I'll send a copy to you and Jamie now, of basically what are those categories of substances that we all know you should never combine.

**Arien Malec – RelayHealth – VP, Product Management**
And likewise for interactions there are a short list of classes that are problematic, there's a much longer list that you need to worry about, but there's a short list that are frequently associated with patient harm.

**Farzad Mostashari – Office of the National Coordinator for Health Information Technology**
This is Farzad. You also have to be thinking about the mechanism for just ... dissemination and maintenance. We, through some work through our ... the past two years funded the development of really high level scientific expert, national experts initially focused on what are the most important drug-drug interactions to include, and then it shifted to the inverse of that, what are common drug-drug interactions that often have overrides associated with them to reduce the alert fatigue issue. And so we commissioned and have this content but there really wasn't a clearly identified way for either figuring out how to maintain this moving forward absent ongoing federal funding for it, and B, to disseminate it and get it actually to impact what a provider sitting in their solo practice sees appear on their computer screen. The lesson for that for me is before we go out and develop various lists and compendia, or directory content like that we should pay very close attention to who's going to use it and why they would use it and how it's going to be maintained over time.

**John Halamka – Harvard Medical School – Chief Information Officer**
Very good.

**M**
This is ..., if I can just comment on that quickly, it seems to me that the way this gets disseminated is in those four companies' products for an organization if we could live without one of them we would, and we cannot. And I'm sure that's true for smaller organizations more so. The cost of configuring and/or customizing it to make it a little more usable and useful is very high, and well out of the range of practically all organizations. So I think that's back to my suggestion about certification, if there were some very minimal certification requirement that would, for one thing, have the effect of relieving these four companies concerns about legal liability, which is part of why they produced such an unusable product, and I think that if that could be negotiated that would be the way to make this information available to users. Now, it doesn't answer your other question, Farzad, about who is going to be the custodian for what would need to be really a national library to be very useful.

**John Halamka – Harvard Medical School – Chief Information Officer**
Thank you. And Wes, I think you have the last word on this topic.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**
Thanks. I was actually fascinated by both the discussions on RxNORM and substances in general and the relationship between SNOMED for problem and ICD-10. I'm going to focus on the latter. I know that Cris has been involved in some work on creating mappings between SNOMED and ICD-10, is that the topic of the paper that you're alluding to, John?

**John Halamka – Harvard Medical School – Chief Information Officer**
In general we were looking at where is ICD-10 best used, where is it problematic, what is the evidence internationally that makes a difference, and why is SNOMED actually quite helpful in many contexts, and ... has been circulated around. Mary Jo was very timely.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**
One of the questions that I've never completely understood is the assumption that the problem, a specific field in the EHR, determines the numerator or denominator for various quality computations. It would be ideal to state those computations in terms of the same problem code that is used in the EHR, but we all know that the actual business of creating problem entries for patients in the EHR, the computer is trying

its best to track a very dynamic and social process among multiple physicians caring for the patients and the simple notion that the problem list is a complete list of the problems as identified for the purpose of quality reporting is probably naïve. So I'm wondering whether the apparent notion here that there is a clear automatic mapping from the SNOMED description of a problem and the appropriate categorization of a problem for purposes of billing or workload tracking in environments where there isn't a direct reimbursement is even feasible. I can understand it being possible to compute a SNOMED representation for an ICD-10 code, +/- an NOS here or there. What I can't understand is whether the ... that drives appropriate billing can be generated out of what's appropriate clinically.

**John Halamka – Harvard Medical School – Chief Information Officer**
Jamie, you're probably best able to answer that given the Kaiser work on the conversion medical terminology.

**Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy**
Well, I think that there are cross-maps from the clinical problem coding to the billing coding of the encounter diagnosis that are widely used that have been published by NLM, but there are also efforts underway in IHT SDO to publish an international standard map which I think actually in our last committee meeting we looked at a preview of an NLM making that service available on the Web for interactive lookup, so I think those cross-maps are available, they're used. I'm not sure if that answers the question.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**
It's not clear to me –

**Farzad Mostashari – Office of the National Coordinator for Health Information Technology**
Wes, this is Farzad. Let me take a crack at it. I think there are two issues in which you're saying, and let me present a straw man for how it might work. First of all, you can't possibly be collecting problem lists only for the purpose of quality measurement. Just like medication lists or smoking or ... or anything else, to make meaningful that requirement it would have to be used in clinical care and coordination. I heard from chief medical ... officers of hospitals who said that the concept of maintaining an active problem list is something we're only doing for meaningful use and it's not working very well, and I heard from others that said we're making use of the concept of an up to date clinical problem list to do our ... and it has become an integral and irreplaceable part of our workflows now. And so I think point one is maintaining that clinical updated problem list has got to be integrated into daily workflows and actually used not just for quality measurement.

And I think the second part of this is assuming that that does happen, that clinical documentation is performed and useful for clinical care as well as decision support quality measurement registry functions and so forth, then could we reduce the work if we take, given that you have accurate, up to date clinical documentation, could that reduce the amount of work required to generate the information needed for the billing ... and whether there could be computer assisted suggestions about well, you already said in the clinical documentation the person has kidney failure and they have diabetes and they have whatever, these are some ICD-10 codes that would go along with that instead of you having to pick from the 200,000 codes that you may want that may theoretically be in play. So that's the two step, I think, in terms of theory of the case.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**
That's very helpful. Just trying to line this up along with specific deadlines created by the various regulatory frameworks, so there is, I guess, I'm not sure whether it's a requirement or it's a suggestion, that for the 2014 set of requirements problems be documented using SNOMED concepts. There is an unknown date certain for billing using ICD-10 right now, there is a reasonable belief that the generating of the bill would not be automated by going from SNOMED concepts but could be assisted by going from SNOMED concepts in the problem. So I guess the question we need to resolve is whether there is a finite set of complex SNOMED concepts that represents a problem, or whether a problem is pretty open-ended as per the discussion from David.

**John Halamka – Harvard Medical School – Chief Information Officer**

So a robust discussion, and I'm sure as we have another hour and a half coming up with the Clinical Operations Workgroup and Vocabulary Taskforce we'll add the discussion to that agenda.

**Jim Walker – Geisinger Health Systems – Chief Health Information Officer**
John, this is Jim. Could I just make one quick comment on that?

**John Halamka – Harvard Medical School – Chief Information Officer**
Sure.

**Jim Walker – Geisinger Health Systems – Chief Health Information Officer**
I want to suggest, Wes, that what we need is a two tiered way of looking at this. If you view the problem list as it's viewed in healthcare and medical theory and education, but often not in practice, God knows, as the model for the patient list, which is inadequate but still represents the patient's reality well enough that clinicians can look at it and have a fairly clear idea of where they need to start in their thinking and working, then there are a certain set of problems, that is a very small set maybe, a couple of hundred, that represents 95% or 99% of clinical volume, and then another set that are extremely sub-specialized and represent a given patient's unique and very special reality. So I think when we think about what this needs to be, it needs to be a small set, certainly in our practice a small set of very clearly recognizable problems that entail clear care plans, or at least broad outlines of care plans to doctors and nurses and case managers, and then another set where a sub-specialist needs to be able to say whatever they need to say about this patient's maybe highly unusual situation. But that can actually be negotiated far more manageably than one might think if one looked at this as a single problem.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**
That's part of what I was getting at when I talked about there being social interactions among physicians in terms of how they view the problem list or what problems are on there. But what I'm basically concerned about is that we have a lot of hypothesis here and some specific regulatory deadlines that require certification and require meaningful use that are not flexible with regard to verifying the hypotheses. I'd like to make sure that we pick a unit of progress, a path of least regret, that is manageable in this time frame and leaves open all of the possibilities that are being described here, if we in fact find that there's not enough body of experience to totally regulate what might ultimately be done in the 2014 time frame.

**John Halamka – Harvard Medical School – Chief Information Officer**
A very good summary of the issues, thanks very much, Wes. We now are running a little bit behind, but if look at the agenda going forward we will have somewhat, I think, less controversial topics. But hey, Jim Walker, you are next up for the Clinical Quality Workgroup, and having read your presentation I'm sure we'll have the same broad approval as ... .

**W**
There's your challenge, Jim.

**Jim Walker – Geisinger Health Systems – Chief Health Information Officer**
Although not the stunning depth and breadth of work that Liz's represents, so I want to thank all of the members of the Quality Workgroup and the increasingly helpful staffing from ONC in doing this work. I'll go to the second slide, the NPRM comments that we reviewed included those on the clinical decision support, clinical information reconciliation, quality measures, and problem lists. We've had one meeting and so our comments at this point are preliminary and we haven't really had a chance to sift them and prioritize them yet.

The second thing that we've done is establish the two Tiger Teams that we'll be dividing into to get the work done. The one is going to focus on the essential components of what a usable and useful quality measure would be, and then you can see the specifications that are at least the beginning with that Tiger Team, led by Karen Kmetik, will be addressing. The second Tiger Team that I will be leading will be addressing value sets fundamentally and trying to identify value sets and other components that will be usable and useful for people. The next slide we just have a set of preliminary NPRM feedback that I'm

not going to read or try to characterize for you at this point, but we will be furthering that, and particularly ordering and prioritizing it so that we can come back to you at the next meeting with the things that we think are the most important and then some other things that may be useful to ONC but are more in the nature of style or communication issues. I don't know if Karen's on the line. I think that's really what we have to report at this point.

**John Halamka – Harvard Medical School – Chief Information Officer**
Okay, Jim. Any questions for Jim Walker?

**Jim Walker – Geisinger Health Systems – Chief Health Information Officer**
I'm sorry, I had to step out for just two seconds. I'm back. Go ahead, John.

**John Halamka – Harvard Medical School – Chief Information Officer**
Anyway, so ... address.

**Jim Walker – Geisinger Health Systems – Chief Health Information Officer**
This is Jim. I just had too much tea and I had to run for just a second. You were just too quick.

**John Halamka – Harvard Medical School – Chief Information Officer**
Yes. Anyway, I'm looking at my queue of questions here and I do not have anyone with a card raised. Any comments or questions? Wow, you are less controversial than Liz, so clearly there's a lot of work ahead for the Clinical Quality Workgroup and I want to thank you for all the work so far.

**Jim Walker – Geisinger Health Systems – Chief Health Information Officer**
Thanks.

**John Halamka – Harvard Medical School – Chief Information Officer**
And next up we have the update from the Consumer Engagement Power Team, newly formed and with Leslie Kelly Hall volunteering to serve as chair. Tell us a bit about your scope, your charter, and the next steps.

**Leslie Kelly Hall – Healthwise**
Thanks, John. We're pretty excited about this, and had a good deal of people volunteering and agreeing to participate ... in that formation stage, and I would like to acknowledge Mary Jo's great work and commitment to this and getting things done in a very quick way. Next slide, please.

Our charge is to assess the standards and certification NPRM and provide recommendations for strengthening consumer patient engagement components. That said, that's not just the patient engagement specific recommendations in the NPRM, but as a whole, in the main, the idea that with every electronic medical record activity there is either a corresponding or correlating activity, or may be within a PHR or portal of patient communications. So the power team will prioritize recommendations to enable patients to participate as partners in their care. The patient engagement objectives in meaningful use are being addressed in the Policy Committee. This is really about looking at the overall standards and how they might be further enhanced to promote patients as partners in their care. Next slide.

Here are the members of the group and newly added is Liz, so thank you, Liz, for volunteering. We have a wide range of expertise and thanks to Lygeia we also have patient participants so we hope to have the patients' voice included in this process as well as all of us that work to improve patient engagement. Next slide.

Our meetings, two meetings have been set so far, along with some orientation that we're doing for the patient advocates this week. So we hope to report back soon after these meetings and look forward to any questions or comments the committee might have, please e-mail me and I would be happy to include. That's it.

**John Halamka – Harvard Medical School – Chief Information Officer**

Okay, well any comments? I know certainly consumer engagement is going to be an increasingly important topic, as you've heard thus far in the call, with looking at the transport standards that Dixie's group is doing, looking at some of the content for download standards, as the Clinical Operations Workgroup is doing. We really want to make sure that we're going to provide the right workflow, the right functions that are value-added to patients and families and the standards that support them, especially if there's going to be the notion of downloading a record and then as the patient becomes the steward of their own data, hands it off to others. And the NPRM is very good but on the view and the download we feel maybe a little bit more specificity of what's going to make the patient's experience best is needed, so we will work with you in that regard.

**Leslie Kelly Hall – Healthwise**
Thank you, John.

**Farzad Mostashari – Office of the National Coordinator for Health Information Technology**
Leslie, this is Farzad. As we move beyond just the immediate needs of the NPRM on the clinical side, it would be important for you to have on your parking lot working with other stakeholders, particularly health plans in CMS on the administrative data side as well. We have, I think, some of the biggest insurers in the country who have committed to enabling Blue Button download of personal health information, CMS has already implemented it, and the Office of Personnel Management has plans who wish to serve the federal employee health plans to also make that available, but the question is, there's a standards question there in terms of what information will be included in that code set and how it would be implemented. We probably need to work with other groups, including potentially NCVHS on that question, but I want to make sure that it's on your docket.

**Leslie Kelly Hall – Healthwise**
Thank you very much. We will.

**John Halamka – Harvard Medical School – Chief Information Officer**
Okay, well we now have Dixie Baker presenting the Privacy and Security update and some very thoughtful comments that they've gone through line by line and looked at some of the areas where clarification is needed. Dixie, please go ahead.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Thank you, John. You can just go ahead to the next slide. I only have one slide here, but I will go into a little bit of more detail about our comments. The Privacy and Security Workgroup has completed its review of the NPRM, and first of all, overall we thought that the ONC did a great job of translating our recommendations into standards and certification criteria. We did have a couple of recommendations. The first one has to do with the transport standards, as you may know, there are three transport standards included in the NPRM, and I think ONC already knows that the references, the citations themselves aren't complete and accurate. So although we know that the first two of the three are direct standards, specifications, the third one references SOAP and we think that this has to do with the modular specification that's being developed by the S&I framework, but these need to be clarified, and I know that Steve is aware of that, so I won't go any further.

The other part of it that we're concerned about is that there's confusion as to what actually is required because there's inconsistency between the two certification criteria that referenced these transport standards. The transitions of care certification criterion requires the two direct specifications and says that the SOAP specification is optional, and then they transmit to third parties, certification criterion requires only the two direct specifications and it doesn't even mention the third one, the SOAP. So we think that the criteria need to be consistent to make it less confusing for the vendors in meeting these criteria.

The second area of misunderstanding relates to the patient accessible log. This is in the whole list of patient involvement requirements. Interestingly, I think everybody thought that they understood this and then when we got together we realized that we had different understandings of what it meant. Specifically, there's a requirement for a patient to generate an audit of events and some of us thought that

this requirement to generate this audit log and to make it accessible to patients was derived from the HITECH requirement that required that providers be able to transmit electronic health records to a third party at the request of the patient. So we thought that the accessible log was a log of activities on, if you will, the patient portal, so it would be the log of activities that involve the patient, like viewing their record, logging in, downloading their record, and transmitting it to the third party. But other people interpreted that ability to transmit to a third party more generally as any ... transmission to a third party of record, whether that transmission be requested by the patient or not and whether it be from the portal or not. And so these people then interpreted the requirement for the log to be accessible to patients as being really the accounting of disclosures log that should be accessible to patients. So there's confusion there and then the preamble explanation further confused things, so that really needs to be clarified, the intent of both the audit log that includes the transmission to third parties, as well as what log needs to be made accessible to patients.

The third concern is that there's a certification criterion for secure messaging with patients, but the criteria for allowing a patient to view their records, their health information, and to download their health information doesn't have any security requirements associated with either of those. So we recommended that the same certification criteria that are specified for secure messaging be used to generate another criterion that applies to viewing and downloading. And those criterion standards are really the use of the ... encryption and integrity protection, and the use of authentication. We did discuss, as John mentioned at the beginning, that the NPRM does not cite transport layers, security, TLS, or HTTPS as standard, but actually in discussing it we concluded that it's probably better the way they did, though, because they specified that authentication is required and that they also specified that the ... endorsed encryption and integrity protection are required. And by doing that lower level specification, if you will, without really locking into a protocol, really allows more flexibility as other protocols come along in the future. So we thought the same approach should be applied to download and viewing but we like the approach in general.

The next one, there were a couple of places that referenced that things be restricted to a limited set of users, specifically that the disabling audit, in turning off encryption it said that restrict the ability to do this to a limited set of users. Technology in general can't judge what is limited and not limited, so we simply suggested that the wording be changed to "authorized users." The NPRM says that actions recorded in the audit log must not be capable of being changed, overwritten, or deleted, and we recognize that this would preclude anybody from purging an audit log after the required retention period had lapsed. So we suggested a minor change in wording there.

The NPRM prescribes very specific lists of actions to be audited and the audit data to be collected for each audit. As a general rule we strongly encourage the ONC to use existing standards that are developed by standards development organizations overwriting, creating our own standards. These ... standards have undergone a rigorous process to minimize their vagueness and to make it clear, and they are much more likely to be uniformly interpreted because they are established by SCO organizations. So we recommend specifically that ASPME 214701, which is entitled, "Standard Specification for Audit and Disclosure Logs for Use in Health Information Systems" be incorporated as the standard, or what Doug referred to earlier as incorporation by reference rather than this list of specific standards that would have to be maintained in the regulations, so that any slight change would require a change in the regulation itself. In our original recommendations we recommended ASPME 214701 and we still hold that that would be a better standard to use than to articulate separate actions to be audited in the regulation itself.

And then the final point, reduce the specificity of how patient information may be appended, what this really boils down to is to take the same approach for I as they took for II. They had two sub-items in that particular criterion and we felt that rather than specifying things like it can be faxed or appended as a stand document or as free text, which is what it says now, that it just end after ... supplied information as the next criterion does. So we have included all of our recommendations with the materials distributed today, and we are just starting the development of recommendations for test procedures. This is in support of the work that the Implementation Workgroup that Liz described earlier. Liz has asked our workgroup to specifically address the privacy and security test procedures, so that's what we're starting,

and we're happy to have Will Phelps working with us, thanks to Joy Pritts, and we have NIST support as well. So that's it.

**John Halamka – Harvard Medical School – Chief Information Officer**
Dixie, thanks very much and I think you have highlighted some of the issues that I have heard about with regard to transport and patient access that need some additional clarification, and your group has really done a very detailed job in that spreadsheet document that you sent out. I don't have any questions in queue for you, but are there folks on the committee that have questions of Dixie?

**Leslie Kelly Hall – Healthwise**
This is Leslie. I do, Dixie. I just wanted to get some clarification on the view, download, and transmit for patients. You've discussed it in terms of the patient asking perhaps the originating body to transmit the records on their behalf, and I wanted to make sure we also included the ability to have the patient direct that transmit themselves. Did you mean both, and, or either/or?

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
The HITECH requires that a patient be able to request that a document be sent to a third party. I think how an organization implements that is up to the organization. And the EHR technology has to be able to transmit it to the third party in accordance with the standards in the document. But again, how it's implemented, how that technology is used within an organization is not really determined by the certification criteria and the standards, the standards and certification criteria really just specifies what the EHR technology must be capable of doing.

**Leslie Kelly Hall – Healthwise**
I am confused, because in discussions the ability for the patient to view, download, and transmit, it states that the patient is doing it themselves and that the standards should support that. I think there is confusion that's worth getting clarity on.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Okay, I'll go back to the words and look at what the criterion says. I stand by what I said earlier, though, how technology is implemented is up to the organization, but I'll recheck for you the words.

**Arien Malec – RelayHealth – VP, Product Management**
This is Arien. I actually have a follow up to that.

**John Halamka – Harvard Medical School – Chief Information Officer**
Please, Arien, go ahead.

**Arien Malec – RelayHealth – VP, Product Management**
My reading is actually consistent with Leslie's, in that what's required is to offer the patient the ability to view, download, and, at the patient's discretion transmit. In the Implementation Workgroup we've been talking about the Privacy and Security implications of that, and anybody who hosts generally accessible Web sites and in particular accessible Web sites with broad involvement such as patient involvement, where there's at least two orders of magnitude more people who need to access the Web site, there's a level of privacy and security that needs to be in place, so I know that, for example, John Halamka at ... group has mindful folks who are looking at their ... and looking at their cross-eyed scripting and SQL injection ... factors and looking at their front end patients' password change management procedures to make sure that there's no risk to patients. And I wonder whether there's an appropriate charge, given that we're now including those kinds of patient accessible technologies in both meaningful use and in certification that there's an appropriate charge to the Privacy and Security Workgroup to look at appropriate security practices for patient facing technology and organization ... patient facing technologies.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
I do have the requirement in front of me, and it is to enable a user to provide patients and their authorized representatives with online access to do the following, one is view, one is download, and the third is

transmit to a third party. So it does say that the technology has to enable a patient to be able to transmit it to a third party.

**M**
Yes.

**W**
Correct.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Right. As far as the safety implications, I don't know where to take that comment. It's a good comment. Is there a question?

**M**
Yes, my belief is that there's a higher level of privacy and security requirements given the higher number of people and the lower presumption on identity assurance and authentication that anything that is patient facing has both special issues and special risks, and can be potentially a ... factor. So my request is that the Privacy and Security Workgroup look particularly at patient facing, Web accessible technology and look at the privacy and security, both policy and standards that are applicable to that ... .

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Our charter is not to look at policy, but I'll be happy to send that comment over to the Privacy and Security Tiger Team, which several of us are on.

**M**
Yes.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**
This is Wes.

**John Halamka – Harvard Medical School – Chief Information Officer**
The advantage is that Dixie is on every committee so it's easy to transmit this.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
It's not an advantage.

**John Halamka – Harvard Medical School – Chief Information Officer**
Wes, please go ahead.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**
Dixie, it's an advantage for all of us. It's not an advantage for you. I would like to, I hope, amplify Arien's comments, although he may tell me I'm out in left field, it's easy to read the language that you quoted, Dixie, as for all practical purposes implying that an EHR, that a base EHR in that new terminology has to include a patient portal. Now, a vendor may provide that, or any developer may provide that capability themselves. They may provide that capability by making an arrangement with another developer or vendor who provides a modularly certified patient portal capability, and the number of vendors we're talking about, I guess it's probably vendors plus self-developers, if you look at the statistics for certification under Stage 1, numbers about 800. Many of those may be certified for modules that aren't specific to this discussion, but the point is it includes developers from very large organizations, organizations whose architecture is fundamentally hosted on remotely or cloud-based, to at the other extreme end of the spectrum products that are sold as standalone systems with servers being placed in the offices of one clinician practices. Depending on where you are within the spectrum there's more or less likelihood that the number of vulnerabilities associated with adding a Web site for the first time to the product and hosting it in a small practice is a pretty substantial risk. And I think given that there are alternatives such as working with a third party that's modularly certified I think Arien is asking how do the proposed rules in their final thing, balance that risk against the need to provide access to patients.

**John Halamka – Harvard Medical School – Chief Information Officer**
And, Wes, you said it so much better than I did.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
I admit, Wes did say it a lot better. Yes, I think that that's a really good point. It's an excellent point, because there are clearer risks, we've all used Web sites to try to buy products and then decided not to buy it from that Web site because it didn't meet our own personal requirements for safety. I don't know, I would be interested in what you, Arien and others would recommend in terms of where we take that. I think that it's a very, very valid concern. But it's not an EHR concern really, it's more an operational risk. I don't know what to do with it.

**John Halamka – Harvard Medical School – Chief Information Officer**
I guess what I'm proposing, at least one thing to do with it is to make clear that when you transition from being a controlled, installed technology that exists within the security boundary of the practice to Web hosting on behalf of consumers, that there are clear security practices and technology requirements that go along with that. And, Dixie, you're right that this area is confusing because we've got governance and a hopefully soon to be released governance ANPRM, we've got the Privacy and Security Tiger Team, this spans policy and security standards, but I think the way that Wes described it is exactly the way I've been thinking about it, as you're potentially asking organizations that are used to managing privacy and security within a small boundary that are suddenly going to the big bad Web –

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Yes.

**John Halamka – Harvard Medical School – Chief Information Officer**
... and I think we need to be very clear about what you're taking on, and then on the other parts of this also provide a path within a core EHR where those organizations can work with a third party that knows how to deal with the big, bad Web to get those requirements met.

**M**
Is this a Privacy and Security Tiger Team policy question?

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
Yes, I think it is. I'll make sure that it gets to the Privacy and Security Tiger Team.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**
I would argue that after that coordination there's a good chance that it gets reflected back our direction with requesting answers to some specific questions such as are there special security certification requirements associated with the modules that provide the patient portal and that provide Web access to consumers to information created by electronic health record systems. And I thought there was something else, but I can't think of it right now.

**John Halamka – Harvard Medical School – Chief Information Officer**
Very good. Any other comments on this topic, committee members?

**Jim Walker – Geisinger Health Systems – Chief Health Information Officer**
John, this is Jim. So, this is a matter of approach that's reflected in language. Everyone on this call is a patient, or practically everyone. There might be a few young people who aren't. Practically everyone on this call is a consumer. And what we're talking about in this context and, by the way, in the patient engagement committee membership context is ... the difference between whether you buy healthcare services or you don't and whether you receive professional healthcare services or you don't. It's whether you are supposed to have training and obliged by your profession to do privacy and security practices as part of your work, or whether you're not. I think if we talked about lay people and professionals, or something like that, it wouldn't be quite so unclear what it is we're talking about in many of these contexts.

**Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences**
I think also we can relate it with the financial industry because they've come a long way from the early banking online sites to where they are now, and I think that anybody that uses them is quite aware of that, how much safer they are now than they were initially, or how much safer they feel using them now than they did initially. So these are really good points, very good points.

**Wes Rishel – Gartner, Inc. – Vice President & Distinguished Analyst**
I think we clearly are talking here about, perhaps the first time we've ever talked about access to, given that we have an EHR focus, this is the first time we're talking about access to the EHR by lay people. On the other hand, we've had to deal with whatever the opposite of lay people is, I don't know if it's stand people, or whatever, that are pretty naïve, and I agree with Dixie that there is a level of technology now that is in the spy versus spy way, where the black hats think up some new challenge and the white hats figure out some new defense. There have been a number of iterations like that. My own feeling working with several banks is that the smaller the bank the more obtrusive their security is, so it's harder to log into my savings and loan than it is to Bank America at this point. The issue, though, is how do we create a sufficient level of assurance about the products without ending up doing audits and doing all of the things that banks and credit card companies do to assure security, because they don't think we see that in the budget at this point.

**M**
Wes, --

**Jim Walker – Geisinger Health Systems – Chief Health Information Officer**
... .

**M**
Jim, just really quickly, in my view the difference between a layperson and a professional is not necessarily sophistication. There are very sophisticated lay people and there are very naïve professionals obviously. The difference is obligation. A professional in this context is obligated to practice safety and confidentiality practices at whatever level they're called to, whereas, a patient, there is no obligation, I don't think, for a layperson there is no obligation that they follow safe and secure practices. They might be smart, but I don't believe they can be taken to court or disbarred or anything else for failing to practice safety practices.

**Jim Walker – Geisinger Health Systems – Chief Health Information Officer**
Good point. Thanks.

**John Halamka – Harvard Medical School – Chief Information Officer**
Thanks for that robust discussion, and I'm sure Dixie will follow up with the Privacy and Security Tiger Team and then loop back to us, making sure that there is appropriate guidance to consumers as to what sites and what policies of such sites will ensure the safety and integrity of their data.

Jon Perlin, we have John Derr's presentation on the post-acute care activities, the long term care, but there is an item on cross-workgroup coordination. My sense is, based on yesterday's call with ONC, that we have delineated all of our workgroup activities and made sure that the scope of the actions over the next 30 days is consistent with ONC's need and with the overall yearly work plan, but Jon and Mary Jo, are there other areas of concern for cross-workgroup coordination?

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
First, I appreciate all of the activity and all of the updates. Indeed, the first set of clear cross-cutting activity is in response to the NPRM. Let's mention one in particular, John, and that's that we note that Liz Johnson and Cris Ross have done an absolutely fabulous job in terms of making very practicable, that is practical and pragmatic, the concepts necessary for testing and certification. And it's said that no good deed goes unpunished, but it was suggested by a number of people that there be a liaison or member of the Standards Committee on the Policy Committee Certification Adoption Workgroup, someone who brought forward the immediate knowledge of what the Standards Committee Workgroup was doing, and

had really broad command of the topic, understanding the big picture at both a technical and broader ... application level. And so I'm not surprised then that Liz Johnson's name came forward, and I'd like to put forward her name as the Standards Committee representative to the Policy Committee, if there are no objections from other committee members. Well, Liz, thank you very, very much for not only your hard work, but it's clear that you have the endorsement of your colleagues, and I really appreciate your agreement to take on more work, and I know that we'll look forward to even further continuity of activity between the Policy Committee and the Standards Committee. John, are there some other areas that you'd like to mention?

**John Halamka – Harvard Medical School – Chief Information Officer**
No, recognizing that the focus of our first quarter is getting all these NPRM comments together and making sure that that NPRM is polished to its greatest extent, lots of communication happening among the workgroups, and now, as you suggested with Liz, between the Standards Committee and the Policy Committee bolstering the interplay there, I think we are aligned for meeting ONC's needs, but certainly Farzad or Mary Jo, are there other insights based on all these updates and comments you would have, anything that you want to make sure we don't miss?

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
This is Mary Jo, and I just want to thank you all for being so extraordinarily diligent in your individual tasks and in your cross-cutting communications. You've really helped us a lot, and I think that it means that the work that you turn in will be a really robust and polished product. So thanks to all of you.

**John Halamka – Harvard Medical School – Chief Information Officer**
Okay. So I guess with that, Jon P. that maybe we are just to go to John Derr and then to public comment.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
I think so. John, are you on line?

**John Derr – Golden Living LLC – Chief Technology Strategic Officer**
I'm on line. I had to ask Mary Jo, when I saw the agenda we've been talking about a briefing for everyone for quite a while with Mary Jo, and the strategy was, because this is part of the second quarter action plan, to give both to the Policy Committee and to the Standards Committee a short briefing on what really is long term and post-acute care. And I asked Mary Jo yesterday when I saw the agenda and all that, that would you please be able to postpone this until the April meeting because we wanted to show it first to the Policy Committee and then I would like very much to give it in person and not at a virtual meeting in case there are some questions to do on it. So the bottom line, I asked permission to have it postponed to April. That was granted and so I don't really have the slides to send to you today. I'm a retired Navy captain ... and I just fell on my sword.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
John, no need to fall on your sword, but there might be some introductory or preparatory comments that you'd like to offer in terms of next time.

**John Derr – Golden Living LLC – Chief Technology Strategic Officer**
Yes. ONC is paying a lot of attention to long term post-acute care, which we appreciated, on the S&I committee there's a Longitudinal Care Workgroup. We also, because of the second quarter objectives, we've developed and ONC's calling it a roundtable of thought leaders which will meet on May 3rd in Washington, D.C. At the upcoming S&I committee thing a large number of us will be there and of course I mentioned to you before on June 18th we have our 8th summit on LT Pack HIT, which I'll be sending you the agenda. So we're working also on the comments that Dr. Mostashari asked us to comment on, on page 132 of the ONC proposed rule, which is for certification for non-eligible providers, and we're also working on comments for the CMS proposed rule. So there's a lot of activity going on in our sector and we greatly appreciate the support. So what I was going to do, and what Larry Wolf from Kindred will do next week, I believe, is give a very short 20 minute thing just on what is LT Pack, what it is that we've

been doing up to now, sort of as a precursor to give all of you some background as we go into quarter number two.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
Thanks, John. Any comments or questions for John Derr?

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Jon and folks, this is Mary Jo. I am sorry I didn't relay that to you in a more timely manner, but we are really very pleased that this is one more example of bringing the Standards and the Policy Committees together, Charlene Underwood, who chairs the Meaningful Use Subgroup #3 on Care Coordination, and Leslie Hall sits on that subgroup too, have very enthusiastically embraced the notion of bringing LT Pack issues in through that side. So we're just trying to do a coordinated, integrated approach to make sure that the policy and the standards things are synched up.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
Terrific, thank you. Well, I, for one, am extremely impressed and appreciative of the robust discussion and all of the attention to the NPRM. A lot of work has occurred really not even quite a full month since publication of the federal register, and being that there's just slightly more than a month until the 60 days are completed our time course is a little bit shorter in that certainly we want to provide ONC with our coordinated response and all of the efforts.

Before we go to public comment, let me just do a couple of things. First, again, I want to reiterate my profound appreciation to Mary Jo Deering for her tireless work. I know that members of the committee get e-mails on nights and weekends, but really a very distinguished federal employee to whom we are most grateful, so many, many thanks for that. We will again look forward to working with MacKenzie, but I think that that same gratitude is really due to the entire ONC team, Farzad, Doug, Jodi, and all of the leadership. I know how hard you've been working and it's great, not only as someone who had the privilege of working in healthcare, but someone who experiences healthcare occasionally as a patient, often as an advocate, to see these things coming forward.

Let me turn to also someone to whom a great debt is owed, and that is John Halamka. He's been on virtually every possible activity in between the meetings, and that heroic work is appreciated and I look forward to your closing comments, John.

**John Halamka – Harvard Medical School – Chief Information Officer**
Certainly as you look at the work plan for 2012 the trajectory that we're on is very good, and that we are hitting on all the goals and certainly communication is going to be just extraordinarily important as we close out that 60 day evaluation period and make sure that ONC, our workgroup chairs, and the members of the committee all get in their input and we consolidate it representing the best input from everybody so that ONC can get that NPRM into final form. I equally extend my thanks, and I would offer that Mary Jo Deering keeps the same hours as Judy Sparrow, and we never thought that would be possible, so thank you.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
Well said, John. With that, let us turn then to Mary Jo to ask for any public comments that might be offered.

**Mary Jo Deering – Office of the National Coordinator for Health Information Technology – Senior Policy Advisor**
Thank you very much, everybody. I certainly appreciate the remarks. And at the risk of introducing too much levity after such very complimentary remarks, I think I would paraphrase a certain former president and say that you will still have me to kick around for a while, because we really want MacKenzie to succeed, and so I'll still be handling some of the things like the coordination between the workgroups and the FACAs and things like that. So I'm not abandoning MacKenzie early on in her career.

Operator, would you open the lines for public comment?

**Operator**
(Instructions given.) We have no comments at this time.

**Jonathan Perlin – Hospital Corporation of America – CMO & President**
Okay, well, with that, thank you all for the work that you've already completed and thank you in advance for all of the work ahead. I hope that you do have a chance to enjoy some of the beautiful spring, but also anticipate that this is going to be a very busy season. So with that, we stand adjourned. Thanks, all.

**John Halamka – Harvard Medical School – Chief Information Officer**
Thank you, everybody.

## Public Comment Received During the Meeting

1. HIT Standards Committee March 27, 2012.As part of Meaningful Use 2, the ability of the electronic medical record to receive not only medication allergies, but the electronic medical record needs to be able to receive food allergies and environmental allergies. The three allergy types should also be part of the electronic medical records and part the certification criteria.

2. Agree with Jamie Ferguson comments regarding use of the RXCUI for ingredients, class-based and medication concept allergens. Suggest that Consolidated CDA be aligned with final recommendations.

3. It would be good to have a written set of instruction for patients accessing a patient portal delineating safe practices for Privacy & Security. This would assist aligning expectations of the professional and of the patient.